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PRINCIPAL INVESTIGATOR: Junaidah B. Barnett, Ph.D.

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13. ABSTRACT *(Maximum 200 Words)*

African-American (AA) women have the highest breast cancer mortality rate in the U.S. Despite reports suggesting that breast cancer in AA women might be a biologically more aggressive disease, AA women, especially postmenopausal AA women, remain one of the least studied populations in this country, with very little known about their sex hormone profile. Recent findings have suggested that body fat distribution may be a better marker for breast cancer risk than degree of obesity. This is a 5-year cross-sectional study to determine the association between body fat phenotypes and sex hormone profile in postmenopausal AA women. For year one, we were able to successfully complete all necessary Tasks outlined in our approved statement of work, with the study running smoothly. This is a very challenging study to undertake. Study promotional efforts as well as the process of getting women through the study protocol are highly time-consuming and labor intensive. To date the number of interested callers is 162. Of these, 40 did not return our calls, and 100 have already been telephone screened. Fifteen women are eligible, and 14 will be eligible at a later time. We are actively in the process of getting these women through the study protocol.

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INTRODUCTION:

Breast cancer is a major public health concern for African-American (AA) women in the U.S. AA women experience higher breast cancer mortality rates as well as higher prevalences of obesity and upper body adiposity than Caucasian women. Despite reports suggesting that breast cancer in AA women might be a biologically more aggressive disease, AA women, especially postmenopausal AA women, remain one of the least studied populations in this country, with very little known about their sex hormone profile. Recent findings have suggested that body fat distribution may be a better marker for breast cancer risk than degree of obesity. In this study, we will test the hypotheses that postmenopausal AA women with normal versus upper body fat phenotypes have a sex hormone profile associated with the lowest and highest risk of breast cancer, respectively. This will be a 5-year cross-sectional study comprising 210 healthy postmenopausal AA women (one year postmenopausal up to age 70 years); 70 per body fat phenotype categories of lower ($WHR \leq 0.75$), normal ($0.75 < WHR \leq 0.80$) and upper ($WHR > 0.80$) body fat phenotypes. Blood samples will be collected on two consecutive days for determination of estradiol, free estradiol, percent free estradiol, estrone, estrone sulfate, testosterone, free testosterone, percent free testosterone, androstenedione and sex hormone binding globulin, as well as follicular-stimulating hormone and luteinizing hormone. We will determine the subject's body mass index (BMI) and percent body fat using a Hologic Dual Energy X-ray Absorptiometry (DEXA) scanner and collect other relevant data to enable us to control for established and possible confounding factors such as: medical history including family history of breast cancer and a history of benign breast disease; reproductive history such as age at menarche, age at first birth, and number of children; dietary data; physical activity data and others such as use of alcohol, smoking, and exogenous hormones. Multivariate regression models adjusting for various confounders such as age, BMI or percent body fat, age at menarche, parity, and others such as age at first birth as well as various interaction terms between age and BMI, and age and body fat phenotypes, will be conducted to test our hypotheses. This study will add to the virtually non-existent data on sex hormone profile as it relates to postmenopausal breast cancer risk in normal, lower and upper body fat phenotype AA women, independent of body adiposity. It will help us determine whether or not the current thinking of a positive linear association between WHR and breast cancer risk is correct. If our hypotheses are true, future studies would need to control for body fat phenotype; otherwise study findings may provide misleading conclusions. Further, as body fat distribution is potentially modifiable by lifestyle factors such as diet, smoking, drinking alcohol, and physical activity, the possible identification of certain body fat phenotypes as a marker of a hormonal pattern that may increase breast cancer risk in women is of considerable importance.

BODY:

Statement of Work

Body Fat phenotypes, Sex Hormones, and Breast Cancer Risk in Postmenopausal African-American Women

Task 1. Set up study (Months 1 to 4)

- **inform collaborating bodies (such as the GCRC, NEMC[1], and BONREC[2]) of grant award, set up appointments, and finalize arrangements for conduct of the study using their services**— Accomplished. This encompassed a presentation to the GCRC administrators and nurses about the study, and outlining study needs such as blood drawing services, blood processing and storage protocols, use of examination room for screening appointments and body measurements, as well as need for meals

[1] GCRC, NEMC: General Clinical Research Center, New England Medical Center

[2] BONREC: Boston Obesity and Nutrition Research Center

for subjects after blood drawing following fasting the night before. All these services are provided without any extra cost to the study. The logistics for use of these services have all been worked out and are working smoothly. The PI also met with BONREC administrator and DEXA technician to work out the logistics of DEXA scanning needs for this study. This too is currently working smoothly.

- **start hiring process for the Project and Enrollment Coordinators with the goal of hiring them by the 3rd month, and training the Project Coordinator by the 4th month**—Accomplished; both Project Coordinator now called Research Coordinator, and the Enrollment Coordinator, now called Outreach Coordinator are hired and trained at this time. However, the PI was having some difficulty in hiring the right candidate for the Research Coordinator position. We hired Ms. Laura Snydman, in October, 1999. She left the study in February, 2000, because she decided that the recruitment component, i.e, to advertise the study within the AA community was too demanding and not something she would be interested in doing as part of her role as Research Coordinator. Ms. Christine Gebeshian was hired in March, 2000, but became sick with sciatica soon after that and was bedridden for about two months. We started the hiring process immediately to find a replacement for her. However, Ms. Gebeshian became better and decided to come back to the study in June, 2000. Because of our experience in losing time with Ms. Gebeshian's illness, we decided to hire a back up student assistant, Ms. Jessica Schletter. Ms. Schletter had indicated that she would work as our back up or Assistant Research Coordinator to assist in screening women and taking body measurements throughout the five-year study period. This made it appealing for the PI to have her on the study team. Both Ms. Gebeshian and Ms. Schletter were trained to screen women, and take body measurements. However, the PI was forced to terminate Ms. Gebeshian's employment with the study due to personality difficulties at the end of June, 2000. The PI was for the third time again actively seeking to hire a Research Coordinator for the study. The PI found a suitable candidate, Ms. Nikki Leiser, to fill the position. Ms. Leiser had also indicated an interest to work on the study over the five-year period. This was appealing to the PI who is looking for someone to take on this position long term to ensure the smooth running of the project without the interruption of another hiring process to fill in that position. Ms. Leiser, however, could only start work in September, 2000. With the student taking the role of Research Coordinator to cover study needs till September, 2000, the PI agreed to hire Ms. Leiser with a start date of September 5, 2000. To ensure study continuity in the event that our Research Coordinator takes sick leave or vacation time, and to get additional help for our Research Coordinator in case of increased screening of interested women demands, we realize the need to have someone fill in for the Research Coordinator or to assist her in her duties. This is the reason we are currently requesting approval to introduce a new component of this study, the inter-observer-variability component. We have requested and obtained approval from our Tufts HIRC to undertake an inter-observer variability component of this study to ensure reliable, valid and consistent measurements taken by two or more individuals (Appendix 1). However, this has not been approved by DOD HSSRB as yet due to some additional requirements on their part for which we have not as yet gotten the chance to respond to. We plan to work on meeting all the DOD HSSRB requirements following this report so we can proceed with getting this new component of the study accomplished.

- **purchase all supplies needed for year 1 of study** – Accomplished.

- **finalize, and make copies of all questionnaires, consent forms, and other materials needed for the study**—Accomplished. Please refer to Appendix 2 for final approved copies of the following: (1) main study consent form, donation form and medical release form, and (2) telephone screening questionnaire, 4-day food record (4DFR) booklet, food frequency questionnaire, medical questionnaire, and physical activity questionnaire. The telephone screening and medical questionnaires approval process by Tufts HIRC took a very long time – about three months, a highly unusual situation, due to an overwhelming number of research protocols that needed reviewing by the Tufts HIRC staff at that time, i.e., from

October 27, 1999 to February 17, 2000 (The PI was on maternity leave from November 14, 1999 to February 14, 2000, but was in regular touch with the other study team members throughout that time). Following this the protocol was due for recertification on February 24, 2000. Recertification approval was not given till March 21, 2000. All these meant that the PI was unable to proceed with that phase of the study which screens women and gets them through the study protocol all that time. This coupled with having our Research Coordinator leave the study in February, 2000, due to reasons stated above, gave our study a very slow start. In order to develop our study eligibility criteria and the study questionnaires, the PI did an exhaustive search of the literature, and had several meetings with the study consultants and other experts to obtain their feedback (the study eligibility criteria are enclosed in Appendix 3).

- **develop flyers, and other materials needed for recruitment of the target population, and get approval of the HIRC for use of these materials** – Accomplished. Please refer to Appendix 4 for copies of our approved study flyers, and brochure. Based on feedback from interested women, and the study team members, the PI submitted a revised study flyer and cover letter for the study brochures (see Appendix 5) for approval to the Tufts HIRC, and DOD HSSRB. The Tufts HIRC approved these flyers, but not the DOD HSSRB, as yet. Also developed were enlarged flyers for display at health fairs and other community activities.

Task 2. Recruit subjects and collect data (Months 5 to 54)

- **advertise study to the the AA postmenopausal population using various strategies (old and new), and established and new contacts within the AA community** – These activities are in progress. We have had to undertake aggressive labor intensive advertising. The flyers are critical in these efforts. In general, the response in this population to participation in research activities have been quite reserved, and slow. Many are suspicious, do not like to be a "guinea pig" (these words are heard quite frequently from this population), and are slow to respond to advertisements. Some interested callers said it took them several weeks after receiving the flyer to decide to participate in the study. Currently we have contacted at least 250 churches, 15 community health centers, 20 private organizations, 15 public organizations, and 60 other miscellaneous contacts such as malls, stores, beauty salons, local libraries, elderly housing complexes, radio stations, et cetera. We have also advertised in 22 newspapers and other publications widely read by the Black community and seniors in the Boston area. We have participated in more than 20 health fairs and various other community activities (such as the recent "Million Family March" send off). Flyers have been distributed in the areas highly populated by Blacks in Boston, namely Roxbury, Dorchester and Mattapan. For lack of manpower to distribute flyers to stores, workplaces, etc, we have asked individuals and our various contacts to help distribute our flyers where they will be publicly visible. This approach has been successful to a certain degree, and we have been receiving calls from women who indicated that "someone put up a flyer at work," or that they have seen the flyers where we had not directly contacted those places. Although we do target older women, in general we would ask anyone who is Black (males and younger women) to inform those who may qualify about the study.

  Churches: Despite the great efforts made to reach out to churches, we find this avenue for recruitment a very challenging one, with only very few interested women calling because of our contacts with churches. We are not currently willing to give up approaching churches for recruitment. Feedback obtained has been that there is a need to establish a relationship with the church congregation so as to obtain their trust. This factor actually applies to all efforts, where if there is a level of trust developed between the outreach worker and the potential subjects, the potential subjects are more likely to call to participate. Again this approach is labor intensive. We will need to frequently contact the churches, attend their health fairs, replenish flyers at these churches, and try to specifically target churches with a

larger congregation of older women. Other approaches would be to get information about the study in the church bulletins and to get a member or a minister to announce this study to the congregation after church services. There are churches which publish newsletters and we are also attempting to get information about the study in these church bulletins. In the future, the PI or a study team member will request to give talks about the study at these churches, particularly during activities organized by the women's ministry. We find that individuals who have completed the study are our best proponents. One has actually been actively helping us with the recruitment effort since her participation in September, 2000, attending church services and other community events, reassuring other women that this study will treat them with the utmost respect, and will give them valuable feedback about themselves. In addition, women were also told that the data obtained from their participation will provide much needed data on factors related to increased risk of breast cancer in this population.

Community Health Centers: Our outreach efforts directed at community health centers have been met with varying levels of success. Many of our callers saw flyers at Dimmock community health center for one. Other community health centers would accept flyers, but not that many calls were received by women seeing flyers there. Directors and medical officers of other health centers such as Mattapan community health center, however, are requesting that we provide summary statistics of women living in their areas of service who participated in the study in exchange for their help in recruiting women. We had not been able to agree to this at this time pending approval from DOD HSSRB about this. Following approval, we will meet with these directors and medical officers to explain to them the importance of this study, and the methodology involved, et cetera, and plan to answer their questions to their satisfaction so as to obtain their assistance in recruitment. This will translate into what we see as a major step in our recruitment efforts. Women tend to trust their doctors, and if encouraged to participate in the study by their doctors would tend to do so more than otherwise. For the future we will discuss with the directors and medical officers about the possibility of conducting screenings of women for eligibility at these centers, and even conducting the study there utilizing their blood drawing services, exam room, etc. These will minimize travelling requirements which we hear is a complaint from those interested but have difficulty with transportation. Women can then be arranged to be transported to the New England Medical Center for their DEXA scans. We will continue with attending health fairs organized by the community health centers, and possibly arranging to give talks at the health centers about the study whenever possible.

Newspapers/Other Publications: We have had good success in advertising the study in newpapers and other publications widely read by the Black population. These include the Bay State Banner, Dorchester Reporter, Dorchester Community News, South End News, Black Pages of New England, etc. The only constraint here is the cost of these advertisement which are exhorbitant. However, we will work on pacing these advertisements throughout the second year of this study to ensure they are kept up, but within the study budget.

Other Avenues: The success of our efforts in distributing flyers in stores, libraries, elderly housing developments/complexes have been difficult to determine. Many women who called forget where they saw information about the study. Some merely said, they "saw a flyer." As mentioned below, we were not able to contact a large number of women for various reasons, and this means we are not able to determine how they heard about the study either. We will continue efforts to distribute flyers at these and other places for the second year of this study.

We have also started exploring linking our study website (http:\\www.tufts.edu/med/research/bcrs.html) to those of other organizations, or at least making requests for this, and researched the websites targeting the Black population. We have already identified 70 websites and contacted some of these. We will pursue this effort further in the future. It may be questionable if our target population can be reached successfully through this medium, but we must explore all possible avenues.

New Endeavours Planned for Year Two: As the study is running smoothly now, for the second year of funding, in addition to what we have already mentioned above, we may conduct many or all of the following:

1. Focus groups: we may undertake this activity to determine needs, e.g., transportation needs, as well as to get feedback on our study flyers, what would encourage Black women in this age group to participate in a research study, and other factors we may have overlooked in our first year,
2. Getting the support of Black leaders in the community: we will be identifying more key leaders within the community, especially women leaders, to obtain their support for the study, and help in encouraging our target population to participate in the study. This will form an important component of our study promotional activities for the second year.
3. Press releases: we may do this in newspapers widely read by our target population to give the study the publicity it may need,
4. Contacting cancer (particularly breast cancer) survivors and families groups: we believe these groups will be enthusiastic about helping us inform women about the study. These groups we feel will help promote the study more feverishly given their experiences with cancer/breast cancer or having a family member with the disease,
5. Contacting other previously uncontacted organizations: we will actively continue expanding our contacts, especially those serving our specific target population,
6. Mass mailing: we may work with a mass mailing company, ADVO, to mail information about the study to 77,000 households in areas highly populated by our target group, such as Dorchester, Roxbury, and Mattapan,
7. Be involved in more community activities: we will be more regularly looking out for any worthwhile community events announced in the local newspapers widely read by our target population for study promotional services, and
8. Arrange to give talks about the study: we will arrange to do this at community functions, libraries, women's groups, and other organizations.

- **screen interested women for eligibility** -- This is also in progress. Currently, the total number of telephone calls received from interested women are 162 (Appendix 6). Four women did not leave a telephone number to call them. Of the 158 women with telephone numbers, we have already called 151; 100 of these were already screened over the telephone. Forty women (or 26% of those called) never returned our telephone calls or are "unreachable." The study policy is to try to contact women at least five times before considering them "unreachable." Of those who do not qualify (N=71), reasons for ineligibility include having a disease (N=17; 7 were diabetic and 4 had breast cancer), those with first degree relatives with breast cancer (N=7), still premenopausal (N=11), menopause due to surgery (N=10), and lifestyle and weight issues (N=15). Eight women were no longer interested or changed their minds about participating. Numbers reported here are not static and changes daily.

- **recruit eligible women into study (expected rate of recruitment is 46 per year for years 1, 2, 3 and 4, and 26 for year 5; total N=210)** -- The number of women eligible after telephone screening is 15 (or 15% of those screened). To increase the number of eligible women in this study, two changes in the eligibility criteria were made, and are approved by our Tufts HIRC. These are changing the eligibility criteria to include (1) women who are at least one year postmenopausal from the originally proposed 4 years postmenopausal, and (2) all eligible women regardless of their level of fat intake from the originally proposed women with at least 30% of calories coming from fat. Please refer to Appendix 7 for copies of our letter of request for these changes and the approval letter from Tufts HIRC. There are currently 14 women out of the 100 screened who are interested but do not currently qualify (i.e., women with "pending eligibility"). These do not currently qualify as they just recently either quit smoking, stopped their weight loss regimen, and stopped taking hormones. We will contact them in about 6

months to re-screen them.

To get the eligible women through the study protocol is another challenge. Of the 15 women who are eligible, 10 have completed going through the consent form process and getting instructions on how to complete the various study questionnaires. This takes place during a "screening appointment." To date we have 1 woman with and 4 needing a "screening appointment," 2 with blood drawing and body measurements appointments, and 3 who have already completed going through the study protocol. These numbers are below the expected rate due to various reasons detailed above, with one main reason being our difficulty in getting the right candidate for the Research Coordinator position till later in the study period. Another main factor is that it is a highly time-consuming effort to get many of the eligible subjects through the various study protocol. Many of the questionnaires returned are incomplete, despite careful and clear instructions given by our Research Coordinator. Incomplete questionnaires mean that the Research Coordinator would need to spend a lot of time over the telephone with these subjects to go over the questionnaires to make sure that all needed data are obtained. In addition many of these women "just love to talk!" Conversations with them had to be skillfully manoeuvred to what is key for the study and terminated when the purpose of the interaction is met. The screening appointments were made only after the present Research Coordinator joined the team on September 5, 2000, and was trained. Given the challenges with reaching interested women and getting eligible women through the study protocol, our recruitment status is progressing reasonably well. This is particularly so given we have only actually been doing this (screening appointments and actual data collection) for about almost two months. Other challenges include forgetfulness among these women of appointment times and dates, and not coming for appointments after several repeat "screening appointments." With plans to intensify and better strategize our recruitment efforts for year two, we expect to increase the momentum such that more women will be calling per month (our current number of calls are between 20 and 30 calls per month for the last two months, and already there are 47 calls this month of October). The higher the volume of telephone calls we receive the more likely it is that we will get the number of eligible women going through the study protocol.

Task 3. Manage incoming data, preliminary analyses, and annual report writing (Months 5 to 54)

- **set up datafiles for medical history, socioeconomic, dietary intake, physical activity, anthropometric**—currently the database has already been set up for entry of data from our medical questionnaire (which includes socioeconomic data) and physical activity questionnaire. Due to the small number of women who have gone through the protocol at this time, we are prioritizing data collection activities rather than data entry. Dietary data from 4DFRs are currently being entered by our Nutrition Data Coordinator using the Minnesota Database. Our priority right now would be to screen interested callers and getting them through the study protocol so as to meet our goals for getting the 46 women we had projected we could recruit for year 1 as soon as possible. As the hiring and training process is now behind us, we look forward to focusing more closely on our recruitment efforts to meet our goals for years one and two of the study this coming year.

- **enter and clean data, and undertake all data quality control measures (ongoing)** – we have not currently undertaken this component of our work as indicated above, with the exception of our 4DFR data.

- **conduct preliminary analyses (once a year) for annual report** –not undertaken as yet due to very small number recruited currently, and because our Research Coordinator is focusing on screening women and getting eligible women through the study protocol.

- **prepare report at end of each project year**—Accomplished.

Task 4. Manage blood samples and ship samples for analysis of hormone levels (Months 5 to 54)

- **set up folder for storing blood sample records** –Accomplished.

- **store all blood samples till ready for shipment to Dr. Longcope's laboratory (samples will not be stored longer than 6 months prior to shipment)**—Blood samples for hormone determinations are stored at the GCRC, NEMC, at –70 degrees Centigrade.

- **ship blood samples to Dr. Longcope's laboratory for hormone analyses every 6 months** – Not accomplished due to small numbers and samples have not been stored for more than 6 months currently.

Task 5. Final analyses and report writing (Months 55 to 60)

- **conduct final data analyses for study** --Will be undertaken at the appropriate time.

- **prepare final report and initial manuscripts** --Will be undertaken at the appropriate time.

KEY RESEARCH ACCOMPLISHMENTS:

None to date.

REPORTABLE OUTCOMES:

None to date.

CONCLUSIONS:

Postmenopausal Black women are one of the most difficult to recruit and thus least studied populations in the U.S.. This is one reason why this study is a very important one, and must continue despite the challenges we have encountered in year one. We find this group of women is even more difficult to recruit for a research study than premenopausal Black women. Based on our first year of research, we are pleased to report that although it is indeed a challenge to recruit postmenopausal Black women for a research study, it is not impossible and can be done. This is a highly labor intensive and time-consuming work. Care must be taken to establish that trust between the researchers and the potential subjects. Patience and perseverence are the two main qualities that our study team has learned to embrace to be successful in getting women to call us and to get them through the study protocol. Subjects must be treated with the utmost care, and respect at all phases of the study. The study success also depends on whether women going through the study protocol had a positive or negative experience. Our study team is culturally very sensitive to the needs of this population, and we do our best to ensure that each subject has a positive experience with the study. With time, we are witnessing increasing support for the study, and many interested callers have volunteered to help distribute our study flyers and inform other women about this study.

Data emanating from this study will add to the virtually non-existent data on the (a) sex hormone profile, and (b) body fat distribution, and body composition of postmenopausal AA women. Significantly more advanced stage and larger tumors, and higher breast cancer mortality rate in AA women compared to Caucasian women have been observed in several studies. In addition to answering questions posed by this main study, the data collected for this study may provide a strong foundation for future work to determine factors associated with these reported racial differences in breast cancer outcomes. Valuable data on dietary intake and physical activity levels in this population will also be obtained. In addition, other scientists within the Tufts community have expressed interest to collaborate with us. We plan to work with these other scientists to either collect additional data and/or use existing data to answer important questions pertaining to heart disease, bone health, and vitamin A metabolism in this population. We will be working very closely with our Tufts HIRC and DOD HSSRB to obtain approval for these research collaborations.

REFERENCES:

None.

APPENDICES:

Appendix 1: Inter-observer-variability consent form approval letter by Tufts HIRC

Appendix 2: Copy of study questionnaires and consent, donation and medical release forms

Appendix 3: Study eligibility criteria list

Appendix 4: Approved study flyers, and brochure

Appendix 5: Revised study flyer and cover letter approved by Tufts HIRC but not by DOD HSSRB

Appendix 6: Study recruitment status

Appendix 7: Letter of our request for approval to change two of the study eligibility criteria, and Tufts HIRC approval letter

APPENDIX 1

New England Medical Center
A Lifespan Partner

TUFTS UNIVERSITY
SCHOOL OF MEDICINE

N.A. Mark Estes, III, M.D.
Professor of Medicine,
Tufts University School of Medicine
Chairman, HIRC

Judy A. Tesnow
Administrator

Barnett, Junaidah PH.D.
COMMHLTH
Box ST-203
TUSM

Re: BODY FAT PHENOTYPES, HORMONES, AND BREAST CANCER IN POSTMENOPAUSAL AFRICAN-AMERICAN WOMEN (DOD)

Login No.: **4354**

PROTOCOL CHANGES ADMINISTRATIVELY APPROVED DATE: 05/30/00

Amendment #: _____ dated: _____ Contact Letter: _____

Interobserver - Variability
Addendum #: ____x____ dated: 05/03/00 Other: Revised Medical Questionnaire

Revision: _____ dated:_____

CONSENT FORM(S): (incorporating protocol changes)

Administratively Approved as Revised: _____ Number of Consent Forms:____

Enclosed for use is a copy of each approved and validated consent form which has been dated with the date of administrative approval and is valid until the date of recertification. Please discard earlier versions.

Must be Revised (see attached copy with changes): _____

No Consent Form Changes: _____

Not Applicable: _____

COMMENTS: Revised Screening Questionnaire **not** approved pending review by the full Committee

Please note that the protocol must undergo full Committee approval at the recertification date.

N A Mark Estes 6/1/00

Signature of Chairman, Vice Chairman, HIRC Member DATE

CC: CSU #744
Abby Shevitz, M.D.

THIS LETTER MUST BE RETAINED FOR YOUR RESEARCH FILES.

Human Investigation Review Committee

750 Washington Street, NEMC #817, Boston, MA 02111
Tel 617 636-7512 Fax 617 636-8394

Body Fat Phenotypes, Hormones and Risk of Breast Cancer in Postmenopausal African-American Women: Determination of Interobserver-Variability

Principal Investigator: Junaidah B. Barnett, Ph.D.
Nutrition Unit, Stearns 203
Tufts University School of Medicine
136, Harrison Avenue, Boston, MA 02111
Medical Monitor: Abby Shevitz, M.D., M.P.H.

Purpose: You are being asked to participate in a study intended to determine variability in measurements between observers. These measurements relate to our 'Body Fat Phenotypes, Hormones, and Risk of Breast Cancer in Postmenopausal African-American Women' study for which we are using more than one observer (or data collector). Findings from this study will allow us to compare differences in readings, and will help determine whether or not we could combine data from our different observers. This subsection of the study will enroll about 10 postmenopausal African-American women.

Screening Procedure: Subjects whose measurements have been taken for the 'Body Fat Phenotypes, Hormones, and Risk of Breast Cancer in Postmenopausal Africa-American Women' study are eligible to participate.

Height, Weight, and Percent Body Fat Measurements: Your height, weight, and percent body fat and body fat distribution will be measured by two or three observers. Percent body fat will be measured with the Futrex machine which uses infrared light to measure body fat at the bicep muscle. Percent body fat will also be measured by the bioelectrical impedance analysis (BIA) method using a Bioelectrical Impedance Plethysmograph. The technique consists of placing electrodes on the surfaces of the hands and feet, and passing a low electric current to the electrodes on the surfaces of the hand and foot to measure resistance and reactance. The intensity of the current utilized is negligible and not detectable by you. However, individuals with pacemakers and implanted defibrillators will be excluded from the study. Measurements will be done three times to calculate percent body fat. This procedure will take less than 10 minutes. All measurements using the futrex machine and the BIA will be done three times by each observer to calculate percent body fat.

Body Fat Distribution Measurements: Body fat distribution will be measured using a tape measure to measure the size of your waist (1 inch above the navel and the narrowest part of your body between the rib cage and the hip), abdomen (the largest part of your body around the abdomen), and hip (the largest part of your body around the buttocks). Anthropometric skinfold measures at the chest, below the shoulder blade, below the waist above the hip bone, biceps, triceps, abdominal, and thigh areas will be taken using the Lange skinfold calipers. Each measurement takes approximately five minutes. All measurements using the tape measure and the skinfold calipers will be done three times by each observer.

Duration of Body Measurements: The duration of your participation is estimated to be one hour per observer.

Participant's initial:_____
Witness' initial:_____

CONSENT FORM

Body Fat Phenotypes, Hormones and Risk of Breast Cancer in Postmenopausal African-American Women: Determination of Interobserver-Variability

Principal Investigator: Junaidah B. Barnett, Ph.D.
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Tufts University School of Medicine
136, Harrison Avenue, Boston, MA 02111
Medical Monitor: Abby Shevitz, M.D., M.P.H.

Benefits: As a participant in this study you will receive data on your height, weight, percent body fat, and body fat distribution measured free of charge. The data obtained in this study may not benefit you but are important in providing information on differences in measurements taken by more than one observer.

Risks: The risks in this study are minimal. All procedures described above are safe, non invasive, and rapid. There are minimal risks associated with the BIA procedure. The electrical current is that of a flashlight battery and is painless.

Telephone Numbers: If you have any questions about the study or experience any problems or research-related injury during the study, you should call one of the following persons:

Dr. Junaidah Barnett	(617) 636-0813 (day)	(617) 325-6789 (eve)
Dr. Abby Shevitz	(617) 636-6726 (day)	(617) 636-4234 page#1812

Participation in this study is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Compensation: Each subject will receive a check for $25 total for participation in this study. Payment will be made upon completion of all data collection procedures. You should receive your check by mail about two weeks after the completion of your participation in the study.

Costs: There will be no additional costs to you for participating in this study.

Confidentiality: All data collected for this study are confidential, and are accessible only to the Principal Investigator and her designated study personnel. Each subject and all her questionnaires will be labeled by a code number to prevent identification of the subject. However, representatives from the U.S. Army Medical Research and Materiel Command may inspect the records of the research in their duty to protect human subjects in research.

Participant's initial:_____
Witness' initial:_____

Ver 1.0/May, 00

CONSENT FORM

Body Fat Phenotypes, Hormones and Risk of Breast Cancer in Postmenopausal African-American Women: Determination of Interobserver-Variability

Principal Investigator: Junaidah B. Barnett, Ph.D.
Nutrition Unit, Stearns 203
Tufts University School of Medicine
136, Harrison Avenue, Boston, MA 02111
Medical Monitor: Abby Shevitz, M.D., M.P.H.

It is the policy of the U.S. Army Medical Research and Materiel Command that data sheets are to be completed on all volunteers participating in research for entry into this Command's Volunteer Registry Data Base. The information to be entered into this confidential data base includes your name, address, Social Security number, study name and dates. The intent of the data base is two-fold: first, to readily answer questions concerning an individual's participation in research sponsored by USAMRMC; and second, to ensure that the USAMRMC can exercise its obligation to ensure research volunteers are adequately warned (duty to warn) of risks and to provide new information as it becomes available. The information will be stored at the USAMRMC for a minimum of 75 years.

PARTICIPANT'S STATEMENT

I have read this consent form and have discussed with Dr.Barnett or her representative the procedures described above. I have been given the opportunity to ask questions, which have been answered to my satisfaction. I understand that any questions I might have asked will be answered verbally or, if I prefer, with a written statement.

I understand that I will be informed of any new significant findings developed during this research study.

I understand that my participation in this study is voluntary. I understand that I may refuse to participate in this study, and that refusal to participate will involve no penalty or loss of benefits to which I might otherwise be entitled. I also understand that if, for any reason, I wish to discontinue my participation in this study whenever, I will be free to do so at any time without penalty or loss of benefits to which I would otherwise be entitled to. Also, if I choose to discontinue this will have no effect on my future care or treatment by my physicians or this hospital.

The United States Department of Defense is funding this research project. Should I be injured as a direct result of participating in this research project, I will be provided medical care, at no cost to me, for that injury. Where private citizens are enrolled, other than medical care that may be provided and any other

Participant's initial:_____
Witness' initial:_____

CONSENT FORM

Body Fat Phenotypes, Hormones and Risk of Breast Cancer in Postmenopausal African-American Women: Determination of Interobserver-Variability

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Nutrition Unit, Stearns 203
Tufts University School of Medicine
136, Harrison Avenue, Boston, MA 02111
Medical Monitor: Abby Shevitz, M.D., M.P.H.

payments specifically stated in the consent form, there is no other compensation for my participation in this research. I understand that this is not a waiver or release of my legal rights. I should discuss this issue thoroughly with the P.I. before I enroll in the study.

If I have any questions concerning my rights as a research subject in this study, I may contact the Human Investigation Review Committee at (617) 636-7512.

I have been informed of the above-described study with its risks and benefits, and I hereby consent to the procedures set forth above. I have received a signed copy of this consent form.

I understand that as a participant in this study my identity and data relating to this research study will be kept confidential, except as required by law, and except for inspections by the study sponsor, the U.S. Army Medical Research and Materiel Command (USAMRMC), and except for the Voluntary Registry Database of the USAMRMC.

_____	_____	_____
Printed name of Participant	Signature of Participant	Date

Permanent Address of Participant:

_____
(street , city, zip code)

I have explained to _____ the nature and purpose of this above described study and the risks involved in its performance. I have answered all questions to the best of my ability.

_____	_____
Principal Investigator/Representative	Date

_____	_____	_____
Printed name of Witness	Signature of Witness	Date

Ver 1.0/May, 00

APPROVED: 05/30/00
VALID THROUGH: 03/21/01

APPENDIX 2

Copy of study questionnaires and consent, donation and medical release forms

CONSENT FORM

Body Fat Phenotypes, Hormones and Breast Cancer in Postmenopausal African-American Women

Principal Investigator: Junaidah B. Barnett, Ph.D.
Nutrition Unit, Stearns 203
Tufts University School of Medicine
136, Harrison Avenue, Boston, MA 02111
Medical Monitor: Abby Shevitz, M.D., M.P.H.

Purpose: You are being asked to participate in a research study intended to determine how body fat distribution is associated with your estrogen and other hormone levels as they relate to breast cancer risk. There is growing evidence that women with upper body fat distribution are at a higher risk of breast cancer than those with lower body fat distribution. This is a cross-sectional study which means that all needed data will be collected from you only once, i.e., you will not be asked to return for another round of data collection once you have completed this study. The data collected will include blood samples, and various body measurements as well as dietary and physical activity data as indicated below. The study will enroll about 210 postmenopausal African-American women.

Screening Procedure: If you choose to participate in this study, screening procedures will be done which will include a dietary and medical history. Body weight and height will also be measured. Those with values not within our eligibility criteria will be excluded.

Blood Collections: Samples of blood will be collected. Each morning for two days a blood sample will be taken (20 ml on the first day, and 40 ml on the second day -- 20 ml is equivalent to about 4 tsp and 40 ml to about 8 tsp). All blood drawing requires an overnight fast (i.e. no foods or liquids other than water); eight hours before the first blood drawing for hormone analyses on day one, and fourteen hours before the blood drawing for lipid analyses on day two. The total amount of blood to be taken for the duration of this study is 60 mls (or 12 tsp).

Assessment of Dietary Intakes: In addition to blood collections, we will assess your usual eating pattern by asking you to complete a Food Frequency Questionnaire and a 4-Day Food Record (4DFR). You will be given clear instructions on how to complete the 4DFR. All foods and beverages consumed on the specified days should be recorded in a booklet; this takes less than 1/2 hour each day.

Percent Body Fat Measurements: Your percent body fat and body fat distribution will also be measured during one of the two days of blood collection. Percent body fat will be measured with the Futrex machine which uses infrared light to measure body fat at the bicep muscle. Percent body fat will also be measured by the bioelectrical impedance analysis (BIA) method using a Bioelectrical Impedance Plethysmograph. The technique consists of placing electrodes on the surfaces of the hands and feet, and passing a low electric current to the electrodes on the surfaces of the hand and foot to measure resistance and reactance. The intensity of the current utilized is negligible and not

Participant's initial:_____
Witness' initial:_____

APPROVED: 03/21/00
VALID THROUGH: 03/21/01

Principal Investigator: Junaidah B. Barnett, Ph.D.
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Tufts University School of Medicine
136, Harrison Avenue, Boston, MA 02111
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detectable by you. However, individuals with pacemakers and implanted defibrillators will be excluded from the study. Measurements will be done three times to calculate percent body fat. This procedure will take less than 10 minutes. A total body DEXA (Dual Energy X-ray Absorptiometry) scanner will also be used to measure your percent body fat. You will be lying down on the device and the X-ray will pass through your body in a fine beam. Information about your body tissue density in the path of the beam will be fed to a computer incorporated in the system, and calculations will be made to determine your percent body fat. The duration of this procedure will be approximately 25 mins. You will be exposed to a maximal radiation exposure of 1.5 mRem, which is comparable to the natural background radiation all people receive normally in a two day period.

Body Fat Distribution Measurements: Body fat distribution will be measured using a tape measure to measure the size of your waist (1 inch above the navel and the narrowest part of your body between the rib cage and the hip), abdomen (the largest part of your body around the abdomen), and hip (the largest part of your body around the buttocks). Anthropometric skinfold measures at the chest, below the shoulder blade, below the waist above the hip bone, biceps, triceps, abdominal, and thigh areas will be taken using the Lange skinfold calipers. Each measurement takes approximately five minutes. Your body fat distribution will also be determined using the procedure mentioned above for the DEXA.

Assessment of Physical Activity: You will also be asked to complete the 'Nurses' Health Study II Physical Activity Questionnaire'. The questionnaire asks for your average time per week spent at various recreational and other activities during the past year. The questionnaire is estimated to take five minutes or less to complete.

Duration of Body Measurements and Blood Drawing: The duration of your participation on the day of body measurements and blood drawing is about 1 3/4 hours. On the day when only blood is drawn the duration of your participation is about 15 minutes.

Benefits: As a participant in this study you will receive, on request, a computerized printout of your dietary intake, and have your blood hormone levels, lipid levels, level of physical activity, and body fat composition and distribution measured free of charge. The data obtained in this study may not benefit you but may provide important scientific information.

Participant's initial:_____
Witness' initial:_____

Body Fat Phenotypes, Hormones and Breast Cancer in Postmenopausal African-American Women

Principal Investigator: Junaidah B. Barnett, Ph.D.
Nutrition Unit, Stearns 203
Tufts University School of Medicine
136, Harrison Avenue, Boston, MA 02111
Medical Monitor: Abby Shevitz, M.D., M.P.H.

Risks: The risks in this study are minimal. All procedures described above are safe, non invasive, and rapid. There are small risks associated with venipuncture which in rare cases results in an infection or an occasional black and blue mark. But, venipuncture performed by an experienced phlebotomist decreases these risks. There are minimal risks associated with the BIA procedure. The electrical current is that of a flashlight battery and is painless. The radiation exposure of 1.5 mRem from the DEXA is equivalent to about 2 days of natural background radiation all persons receive normally, and is not anticipated to have any significant effect.

Telephone Numbers: If you have any questions about the study or experience any problems or research-related injury during the study, you should call one of the following persons:

Dr. Junaidah Barnett	(617) 636-0813 (day)	(617) 325-6789 (eve)
Dr. Abby Shevitz	(617) 636-6726 (day)	(617) 636-4234 page#1812

Participation in this study is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Compensation: Each subject will receive a check for $100 total for participation in this study. Payment will be made upon completion of all data collection procedures. You should receive your check by mail about two weeks after the completion of your participation in the study. If you choose not to complete participating in the study, your payment will be prorated. You will receive $60 if your body measurements were taken and if you have gone through one blood drawing before your withdrawal from the study. For the second blood drawing you will receive $40.

Costs: There will be no additional costs to you for participating in this study.

Participant's initial:_____
Witness' initial:_____

Body Fat Phenotypes, Hormones and Breast Cancer in Postmenopausal African-American Women

Principal Investigator: Junaidah B. Barnett, Ph.D.
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136, Harrison Avenue, Boston, MA 02111
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Confidentiality: All data collected for this study are confidential, and are accessible only to the Principal Investigator and her designated study personnel. Each subject and all her specimens and questionnaires will be labeled by a code number to prevent identification of the subject. However, representatives from the U.S. Army Medical Research and Materiel Command may inspect the records of the research in their duty to protect human subjects in research.

It is the policy of the U.S. Army Medical Research and Materiel Command that data sheets are to be completed on all volunteers participating in research for entry into this Command's Volunteer Registry Data Base. The information to be entered into this confidential data base includes your name, address, Social Security number, study name and dates. The intent of the data base is two-fold: first, to readily answer questions concerning an individual's participation in research sponsored by USAMRMC; and second, to ensure that the USAMRMC can exercise its obligation to ensure research volunteers are adequately warned (duty to warn) of risks and to provide new information as it becomes available. The information will be stored at the USAMRMC for a minimum of 75 years.

Participant's initial:_____
Witness' initial:_____

APPROVED: 03/21/00
VALID THROUGH: 03/21/01

CONSENT FORM

Body Fat Phenotypes, Hormones and Breast Cancer in Postmenopausal African-American Women

Principal Investigator: Junaidah B. Barnett, Ph.D.
Nutrition Unit, Stearns 203
Tufts University School of Medicine
136, Harrison Avenue, Boston, MA 02111
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PARTICIPANT'S STATEMENT

I have read this consent form and have discussed with Dr.Barnett or her representative the procedures described above. I have been given the opportunity to ask questions, which have been answered to my satisfaction. I understand that any questions I might have asked will be answered verbally or, if I prefer, with a written statement.

I understand that I will be informed of any new significant findings developed during this research study.

I understand that my participation in this study is voluntary. I understand that I may refuse to participate in this study, and that refusal to participate will involve no penalty or loss of benefits to which I might otherwise be entitled. I also understand that if, for any reason, I wish to discontinue my participation in this study whenever, I will be free to do so at any time without penalty or loss of benefits to which I would otherwise be entitled to. Also, if I choose to discontinue this will have no effect on my future care or treatment by my physicians or this hospital.

The United States Department of Defense is funding this research project. Should I be injured as a direct result of participating in this research project, I will be provided medical care, at no cost to me, for that injury. Where private citizens are enrolled, other than medical care that may be provided and any other payments specifically stated in the consent form, there is no other compensation for my participation in this research. I understand that this is not a waiver or release of my legal rights. I should discuss this issue thoroughly with the P.I. before I enroll in the study.

I understand that there is a possibility that the blood samples that I am providing under this study may also be used in other research studies and could potentially have some commercial applicability. I will be asked to sign a separate donation consent form allow their use.

Participant's initial:_____
Witness' initial:_____

CONSENT FORM

Body Fat Phenotypes, Hormones and Breast Cancer in Postmenopausal African-American Women

Principal Investigator: Junaidah B. Barnett, Ph.D.
Nutrition Unit, Stearns 203
Tufts University School of Medicine
136, Harrison Avenue, Boston, MA 02111
Medical Monitor: Abby Shevitz, M.D., M.P.H.

If I have any questions concerning my rights as a research subject in this study, I may contact the Human Investigation Review Committee at (617) 636-7512.

I have been informed of the above-described study with its risks and benefits, and I hereby consent to the procedures set forth above. I have received a signed copy of this consent form.

I understand that as a participant in this study my identity and my medical records and data relating to this research study will be kept confidential, except as required by law, and except for inspections by the study sponsor, the U.S. Army Medical Research and Materiel Command (USAMRMC), and except for the Voluntary Registry Database of the USAMRMC.

_____	_____	_____
Printed name of Participant	Signature of Participant	Date

Permanent Address of Participant:

_____

(street , city, zip code)

I have explained to _____ the nature and purpose of this above described study and the risks involved in its performance. I have answered all questions to the best of my ability.

_____	_____
Principal Investigator/Representative	Date

_____	_____	_____
Printed name of Witness	Signature of Witness	Date

APPROVED: 03/21/00
VALID THROUGH: 03/21/01

DONATION FORM

Body Fat Phenotypes, Hormones and Breast Cancer in Postmenopausal African-American Women

Principal Investigator: Junaidah B. Barnett, Ph.D.
Nutrition Unit, Stearns 203
Tufts University School of Medicine
136, Harrison Avenue, Boston, MA 02111
Medical Monitor: Abby Shevitz, M.D.

I understand that the blood samples collected for this study may be used in other research studies and may potentially have some commercial applicability. I understand that these blood samples will be coded with a unique number and there will be no personal identifiers. I voluntarily and freely donate my blood samples to the study sponsor (Tufts University School of Medicine) and hereby assign all right, title, and interest to these items. I will receive a copy of this Donation Form.

Printed name of Participant	Signature of Participant	Date

Printed name of Principal Investigator/ Representative	Signature of Principal Investigator/ Representative	Date

Printed name of Witness	Signature of Witness	Date

Ver 1.0/August, 1999

APPROVED: 03/21/00
VALID THROUGH: 03/21/01

TUFTS UNIVERSITY

School of Medicine

Community Health/Nutrition Infection Unit

CONSENT FOR THE RELEASE OF MEDICAL INFORMATION

Volunteer's Name:_____ Date of Birth:_____

Address:_____
(Street) (Apt. No.)

_____ (____)_____
(city, state, zip) (Telephone)

I hereby authorize _____
(Name of hospital or physician)

to disclose and release to the Nutrition Unit, Department of Family Medicine and Community Health, Tufts University School of Medicine, the following discharge diagnosis in my medical record relating to a medical visit during which I was diagnosed with benign\other breast disease on _____.
(date of medical visit)

Please send the medical record information to:

Junaidah Bajrai Barnett, Ph.D.
Assistant Professor
Nutrition Unit
Department of Family Medicine
and Community Health
Tufts University School of Medicine
136 Harrison Avenue
Boston, MA 02111

I may withdraw this consent by giving written notification to the above party at any time prior to the release of the information.

In the absence of my prior withdrawal, this consent will expire in ninety (90) days after it is signed.

Signature of Volunteer:_____
Date of Request:_____

136 Harrison Avenue
Boston, Massachusetts 02111
Ph: (617) 636-3811
Fax: (617) 636-3810

APPROVED: 03/21/00
VALID THROUGH: 03/21/01

Body Fat Phenotype and Risk of Breast Cancer Study
(Postmenopausal)
SCREENING QUESTIONNAIRE

HOW DID YOU HEAR ABOUT THE STUDY?_____

Date:_____

Name:_____ Permanent Address to mail study results:
Mailing Address:_____ _____
_____ _____
Tel.: day_____ evening_____

Demographics/Anthropometrics/Other
Race: Black _____ White ____ Other_____
Age:_____ Date of Birth:_____
Height_____ Weight_____ % IBW____ BMI_____ How long at this weight?_____
Waist_____ Hip_____ W/H Ratio_____
Have you lost more than 10 lbs in the last 6 months? No _____Yes_____
Are you on a weight reduction regimen? No _____Yes _____
Are you planning to go on a weight reduction regimen? No _____Yes_____
Are you in training for any athletic competition? No ____ Yes_____
Have you smoked in the last 6 months? No _____Yes_____
Do you eat meat? (e.g., red meat, pork, poultry, fish) No _____Yes _____
How many alcoholic drinks do you have per week? _____
History of breast cancer in immediate blood relatives? No_____Yes_____ (mother/sister/daughter)

Hormone Use/Menopausal Status:
Menstrual periods: Have you ever had a period during the last year? No _____Yes _____Uncertain_____
Was your menopause natural? No ____ Yes_____
Have you taken any hormones in the last 6 months? No _____ Yes_____
How many years altogether (please estimate) have you been on hormones after menopause? _____
Did you have any ovary(ies) removed after menopause? No ____ Yes _____ , if Yes, how many? _____
Uncertain_____

Breast Health/Other Medical Conditions:
Have you ever had breast cancer? No _____ Yes_____
Have you ever had a biopsy proven adenoma (benign tumor) of the breast? No ____ Yes _____
Have you ever had breast surgery? No _____ Yes____, if yes: please explain:_____
_____
Do you have any medical conditions? Bowel Disease Thyroid Disease Cancer Diabetes
Renal Disease Heart Disease Liver Disease HIV+
Other_____
Are you currently on any medications? No____Yes____, if Yes what?_____
How long?_____

Intake of Foods/Vitamins/Supplements/Herbal Medications:
Are you on a special diet? No _____Yes____, if Yes, please explain:_____
Have you been eating the same way in the last 2-3 months? Yes ____No_____, if No, please explain:
_____
Do you take vitamins? No_____Yes_____, if Yes, what type?_____
How often?_____
Do you take any over the counter supplements or herbal medications for menopause/for other reasons?
No_____Yes_____, if Yes, what?_____ How often?_____
Do you consume any soy/soy products? No _____Yes_____, if yes how much?_____

Please note how many times per day/week/ or month you eat the following food items:

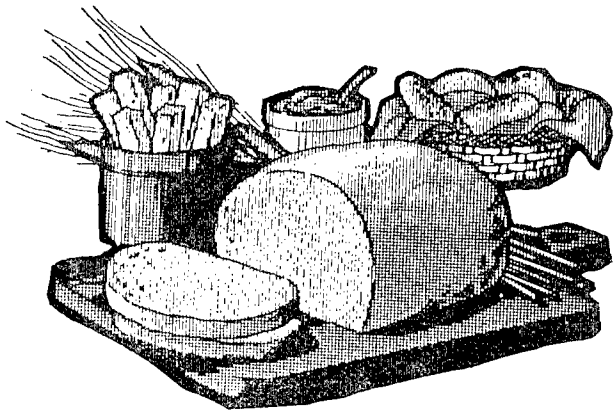
Red Meat No____ Yes____
Beef_____
Pork_____
Ham_____
Veal_____
Chicken w/skin_____
w/out skin_____
Lunch meat_____
Hot dog_____
Other meats_____
Pizza_____
Prepared entrees_____
_____

Milk_____type_____
Cheese_____type_____
Yogurt_____type_____
Ice cream_____
Donut, muffin, croissant,bagel
_____
Cookies_____
Cake/Pie_____
Candy bars_____
Chips/doritos_____
Crackers_____Kind_____
Nuts/seeds_____

Eggs_____
Coffee, Tea_____
Alcohol_____
Other drinks_____
Salad dressing_____
Oil_____
Butter_____
Margarine_____
Spreads:cream cheese, PB
_____
Fast Food (ie. french fries)
_____
Other _____

Other Information/Notes:

FOOD QUESTIONNAIRE



This form asks about your usual food intake.
It takes about 30 minutes to complete. Please follow these instructions:

- Answer each question as best you can – estimate if you aren't sure.
- Use only a No. 2 pencil.
- Be certain to completely blacken in each of your answers, and erase completely if you make any changes.

CORRECT MARK: ●
INCORRECT MARKS: ⊘ ⊗ ◒ ⊙

PLEASE PRINT YOUR NAME IN THIS BOX.
PLEASE DO NOT WRITE OUTSIDE THE BOXED AREA.

1. IDENTIFICATION NUMBER

0	0	0	0	0	0	0	0	0
1	1	1	1	1	1	1	1	1
2	2	2	2	2	2	2	2	2
3	3	3	3	3	3	3	3	3
4	4	4	4	4	4	4	4	4
5	5	5	5	5	5	5	5	5
6	6	6	6	6	6	6	6	6
7	7	7	7	7	7	7	7	7
8	8	8	8	8	8	8	8	8
9	9	9	9	9	9	9	9	9

2. SEX

- ○ Male
- ○ Female

3. AGE

- ○ Less than 20
- ○ 20-29
- ○ 30-39
- ○ 40-49
- ○ 50-59
- ○ 60-69
- ○ 70+

4. TODAY'S DATE

	DAY	YEAR
○ Jan		
○ Feb		
○ Mar	0 0	91 ○
○ Apr	1 1	92 ○
○ May	2 2	93 ○
○ Jun	3 3	94 ○
○ Jul	4	95 ○
○ Aug	5	96 ○
○ Sep	6	97 ○
○ Oct	7	98 ○
○ Nov	8	99 ○
○ Dec	9	00 ○

5. WEIGHT pounds

0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

6. HEIGHT ft. in.

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
	8
	9
	10
	11

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112598

7. **Do you smoke cigarettes now?**

○ No

○ Yes **IF YES, on the average, about how many cigarettes a day do you smoke now?**

○ 1 - 5 ○ 6 - 14 ○ 15 - 24 ○ 25 - 34 ○ 35 or more

8. **About how many times have you gone on a diet to lose weight?**

○ Never ○ 1 - 2 ○ 3 - 5 ○ 6 - 8 ○ 9 - 11 ○ 12 or more

9. **During the past year have you taken any vitamins or minerals?**

○ No ○ Yes, fairly regularly ○ Yes, but not regularly

IF YES, what do you take fairly regularly?

VITAMIN TYPE	NUMBER OF TABLETS								FOR HOW MANY YEARS?				
	NONE	1-3 PER WEEK	4-6 PER WEEK	1 PER DAY	2 PER DAY	3 PER DAY	4 PER DAY	5+ PER DAY	LESS THAN 1 YR	1-2 YEARS	3-5 YEARS	6-9 YEARS	10+ YEARS
Multiple Vitamins													
Stress-tabs type	○	○	○	○	○	○	○	○	○	○	○	○	○
Therapeutic, Theragran type	○	○	○	○	○	○	○	○	○	○	○	○	○
One-a-day type	○	○	○	○	○	○	○	○	○	○	○	○	○
Other Vitamins													
Vitamin A	○	○	○	○	○	○	○	○	○	○	○	○	○
Vitamin E	○	○	○	○	○	○	○	○	○	○	○	○	○
Calcium or Tums	○	○	○	○	○	○	○	○	○	○	○	○	○
Vitamin C	○	○	○	○	○	○	○	○	○	○	○	○	○

10. **If you take Vitamin E or Vitamin C:**

How many units per Vitamin E tablet? ○ 100 ○ 200 ○ 400 ○ 1000 ○ Don't know

How many milligrams per Vitamin C tablet? ○ 100 ○ 250 ○ 500 ○ 1000 ○ Don't know

11. **Do you regularly take pills containing any of these nutrients?**

○ No or don't know ○ Iron ○ Beta-carotene

○ Zinc ○ Selenium ○ _____

12. **What kinds of fat do you *usually* use in cooking (to fry, stir-fry, or saute)? Mark only one or two.**

○ Don't know or don't cook ○ Lard, fatback, baconfat ○ Pam or no oil ○ Crisco

○ Stick margarine ○ Butter ○ Soft tub margarine ○ Oil

○ 1/2 butter, 1/2 margarine ○ Low calorie margarine

13. **What kinds of fat do you *usually* add to vegetables, potatoes, etc.? Mark only one or two.**

○ Don't add fat ○ Lard, fatback, baconfat ○ Low calorie margarine

○ Stick margarine ○ Soft tub margarine ○ 1/2 butter, 1/2 margarine

○ Butter ○ Whipped butter ○ Crisco

14. **When you eat the following foods, how often do you eat a low-fat or non-fat version of that food?**

CHEESE ○ Always low-fat ○ Sometimes ○ Rarely low-fat

ICE CREAM/YOGURT ○ Always low-fat ○ Sometimes ○ Rarely low-fat

SALAD DRESSING ○ Always low-fat ○ Sometimes ○ Rarely low-fat

15.

	SELDOM/NEVER	SOMETIMES	OFTEN/ALWAYS
a. How often do you add salt to your food?	○	○	○
b. How often do you add pepper to your food?	○	○	○
c. How often do you eat the skin on chicken?	○	○	○
d. How often do you eat the fat on meat?	○	○	○

16. About how often do you eat the following foods from restaurants or carry-outs? Remember to think about all meals (breakfast, lunch, dinner or snacks).

RESTAURANT FOOD	NUMBER OF VISITS LAST YEAR						
	NEVER IN PAST YEAR	1-4 TIMES PAST YEAR	5-11 TIMES PAST YEAR	1-3 TIMES A MONTH	ONCE A WEEK	2-4 TIMES A WEEK	ALMOST EVERY DAY
Fried chicken	○	○	○	○	○	○	○
Burgers	○	○	○	○	○	○	○
Pizza	○	○	○	○	○	○	○
Chinese food	○	○	○	○	○	○	○
Mexican food	○	○	○	○	○	○	○
Fried fish	○	○	○	○	○	○	○

17. This section is about your *usual* eating habits over the past year.

FIRST: Mark the column to show how often, on the average, you ate the food during the past year. Please BE CAREFUL which column you put your answer in.

SECOND: Mark whether your usual serving size is small, medium or large. Please DO NOT OMIT serving size.

ADDITIONAL COMMENTS:

- Please DO NOT SKIP any foods. If you never eat a food, mark "Never or less than once a month."
- A small serving is about one-half the medium serving size shown, or less.
- A large serving is about one-and-a-half times the medium serving size shown, or more.

SAMPLE: This person ate a medium serving of rice about twice per month and never ate squash.

TYPE OF FOOD	HOW OFTEN									HOW MUCH			
	NEVER OR LESS THAN ONCE PER MONTH	1 PER MON	2-3 PER MON	1 PER WEEK	2 PER WEEK	3-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2+ PER DAY	MEDIUM SERVING	YOUR SERVING SIZE		
											S	M	L
Rice	○	○	●	○	○	○	○	○	○	3/4 cup	○	●	○
Winter squash, baked squash	●	○	○	○	○	○	○	○	○	1/2 cup	○	○	○

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TYPE OF FOOD	HOW OFTEN									HOW MUCH			
	NEVER OR LESS THAN ONCE PER MONTH	1 PER MON	2-3 PER MON	1 PER WEEK	2 PER WEEK	3-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2+ PER DAY	MEDIUM SERVING	YOUR SERVING SIZE		
											S	M	L
FRUITS AND JUICES													
EXAMPLE: Apples, etc.	○	○	○	●	○	○	○	○	○	1 medium or 1/2 cup	○	●	○
Apples, applesauce, pears	○	○	○	○	○	○	○	○	○	1 medium or 1/2 cup	○	○	○
Bananas	○	○	○	○	○	○	○	○	○	1 medium	○	○	○
Peaches, apricots (fresh or canned	○	○	○	○	○	○	○	○	○	1 medium or 1/2 cup	○	○	○
Cantaloupe (in season)	○	○	○	○	○	○	○	○	○	1/4 medium	○	○	○
Cantaloupe (rest of year)	○	○	○	○	○	○	○	○	○	1/4 medium	○	○	○
Watermelon (in season)	○	○	○	○	○	○	○	○	○	1 slice	○	○	○
Strawberries (in season)	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Oranges	○	○	○	○	○	○	○	○	○	1 medium	○	○	○
Grapefruit	○	○	○	○	○	○	○	○	○	1/2 medium	○	○	○
Orange juice or grapefruit juice	○	○	○	○	○	○	○	○	○	6 ounce glass	○	○	○
Fruit drinks with added vitamin C, such as Hi-C	○	○	○	○	○	○	○	○	○	6 ounce glass	○	○	○
Any other fruit, including berries, fruit cocktail, grapes	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
BREAKFAST FOODS													
High fiber, bran or granola cereals, shredded wheat	○	○	○	○	○	○	○	○	○	1 medium bowl	○	○	○
Highly fortified cereals, such as Total, Just Right or Product 19	○	○	○	○	○	○	○	○	○	1 medium bowl	○	○	○
Other cold cereals, such as corn flakes, Rice Krispies	○	○	○	○	○	○	○	○	○	1 medium bowl	○	○	○
Cooked cereal, or grits	○	○	○	○	○	○	○	○	○	1 medium bowl	○	○	○
Milk on cereal	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Sugar added to cereal	○	○	○	○	○	○	○	○	○	2 teasp	○	○	○
Eggs	○	○	○	○	○	○	○	○	○	1 egg=sml 2 eggs=med	○	○	○
Bacon	○	○	○	○	○	○	○	○	○	2 slices	○	○	○
Sausage	○	○	○	○	○	○	○	○	○	2 patties or links	○	○	○

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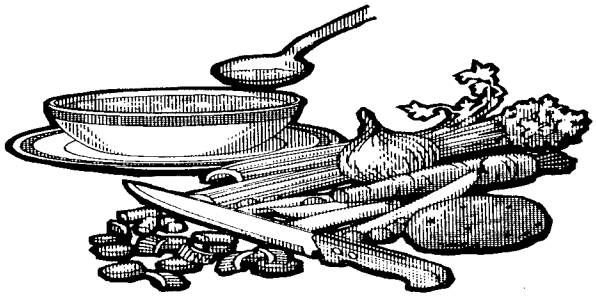
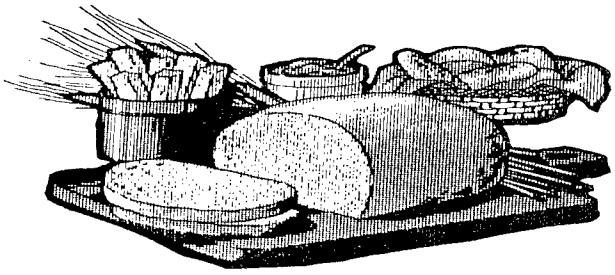
TYPE OF FOOD	HOW OFTEN									HOW MUCH			
	NEVER OR LESS THAN ONCE PER MONTH	1 PER MON	2-3 PER MON	1 PER WEEK	2 PER WEEK	3-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2+ PER DAY	MEDIUM SERVING	YOUR SERVING SIZE		
											S	M	L
VEGETABLES													
String beans, green beans	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Peas	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Chili with beans	○	○	○	○	○	○	○	○	○	3/4 cup	○	○	○
Other beans such as baked beans, pintos, kidney, limas, and lentils	○	○	○	○	○	○	○	○	○	3/4 cup	○	○	○
Corn	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Winter squash/baked squash	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Tomatoes, tomato juice	○	○	○	○	○	○	○	○	○	1 medium or 6 oz. glass	○	○	○
Red chili sauce, taco sauce, salsa picante	○	○	○	○	○	○	○	○	○	2 tablesp	○	○	○
Broccoli	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Cauliflower or brussels sprouts	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Spinach (raw)	○	○	○	○	○	○	○	○	○	3/4 cup	○	○	○
Spinach (cooked)	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Mustard greens, turnip greens, collards	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Cole slaw, cabbage, sauerkraut	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Carrots, or mixed vegetables containing carrots	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Green salad	○	○	○	○	○	○	○	○	○	1 medium bowl	○	○	○
Regular salad dressing & mayonnaise, including on sandwiches or on potato salad, etc.	○	○	○	○	○	○	○	○	○	2 tablesp	○	○	○
French fries and fried potatoes	○	○	○	○	○	○	○	○	○	3/4 cup	○	○	○
Sweet potatoes, yams	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Other potatoes, including boiled, baked, mashed & potato salad	○	○	○	○	○	○	○	○	○	1 medium or 1/2 cup	○	○	○
Rice	○	○	○	○	○	○	○	○	○	3/4 cup	○	○	○
Any other vegetable, including cooked onions, summer squash	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Butter, margarine or other fat added to veg., potatoes, etc.	○	○	○	○	○	○	○	○	○	2 pats	○	○	○

TYPE OF FOOD	HOW OFTEN									HOW MUCH			
	NEVER OR LESS THAN ONCE PER MONTH	1 PER MON	2-3 PER MON	1 PER WEEK	2 PER WEEK	3-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2+ PER DAY	MEDIUM SERVING	YOUR SERVING SIZE		
											S	M	L
MEAT, FISH, POULTRY, LUNCH ITEMS													
Hamburgers, cheeseburgers, meatloaf, beef burritos, tacos	○	○	○	○	○	○	○	○	○	1 medium or 4 oz.	○	○	○
Beef, (steaks, roasts, etc., including sandwiches)	○	○	○	○	○	○	○	○	○	4 ounces	○	○	○
Beef stew or pot pie with carrots or other vegetables	○	○	○	○	○	○	○	○	○	1 cup	○	○	○
Liver, including chicken livers	○	○	○	○	○	○	○	○	○	4 ounces	○	○	○
Pork, including chops, roasts	○	○	○	○	○	○	○	○	○	2 chops or 4 ounces	○	○	○
Fried chicken	○	○	○	○	○	○	○	○	○	2 small or 1 large pce	○	○	○
Chicken or turkey (roasted, stewed or broiled, including on sandwiches)	○	○	○	○	○	○	○	○	○	2 small or 1 large pce	○	○	○
Fried fish or fish sandwich	○	○	○	○	○	○	○	○	○	4 ounces or 1 sandwich	○	○	○
Tuna, tuna salad, tuna casserole	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Oysters	○	○	○	○	○	○	○	○	○	5 pieces, 1/4 cup or 3 oz.	○	○	○
Shell fish, (shrimp, crab, lobster, etc.)	○	○	○	○	○	○	○	○	○	5 pieces, 1/4 cup or 3 oz.	○	○	○
Other fish (broiled or baked)	○	○	○	○	○	○	○	○	○	2 pieces or 4 ounces	○	○	○
Spaghetti, lasagna, other pasta with tomato sauce	○	○	○	○	○	○	○	○	○	1 cup	○	○	○
Pizza	○	○	○	○	○	○	○	○	○	2 slices	○	○	○
Mixed dishes with cheese (such as macaroni and cheese)	○	○	○	○	○	○	○	○	○	1 cup	○	○	○
Liverwurst	○	○	○	○	○	○	○	○	○	2 slices	○	○	○
Hot dogs	○	○	○	○	○	○	○	○	○	2 hot dogs	○	○	○
Ham, bologna, salami and other lunch meats	○	○	○	○	○	○	○	○	○	2 slices or 2 ounces	○	○	○
Vegetable and tomato soups, including vegetable beef, minestrone	○	○	○	○	○	○	○	○	○	1 medium bowl	○	○	○
Other soups	○	○	○	○	○	○	○	○	○	1 medium bowl	○	○	○



TYPE OF FOOD	HOW OFTEN									HOW MUCH			
	NEVER OR LESS THAN ONCE PER MONTH	1 PER MON	2-3 PER MON	1 PER WEEK	2 PER WEEK	3-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2+ PER DAY	MEDIUM SERVING	YOUR SERVING SIZE		
											S	M	L
BREADS, SNACKS, SPREADS													
Biscuits, muffins, (including fast foods)	○	○	○	○	○	○	○	○	○	1 medium piece	○	○	○
White bread (including sandwiches, bagels, burger rolls, French or Italian bread	○	○	○	○	○	○	○	○	○	2 slices	○	○	○
Dark bread, such as wheat, rye, pumpernickel, (including sandwiches)	○	○	○	○	○	○	○	○	○	2 slices	○	○	○
Corn bread, corn muffins, corn tortillas	○	○	○	○	○	○	○	○	○	1 medium piece	○	○	○
Salty snacks, such as potato chips, corn chips, popcorn	○	○	○	○	○	○	○	○	○	2 handfuls or 1 cup	○	○	○
Peanuts, peanut butter	○	○	○	○	○	○	○	○	○	2 tablesp	○	○	○
Margarine on bread or rolls	○	○	○	○	○	○	○	○	○	2 pats	○	○	○
Butter on bread or rolls	○	○	○	○	○	○	○	○	○	2 pats	○	○	○
Gravies made with meat drippings, or white sauce	○	○	○	○	○	○	○	○	○	2 tablesp	○	○	○
DAIRY PRODUCTS													
Cottage cheese	○	○	○	○	○	○	○	○	○	1/2 cup	○	○	○
Other cheeses and cheese spreads	○	○	○	○	○	○	○	○	○	2 slices or 2 ounces	○	○	○
Flavored yogurt, frozen yogurt	○	○	○	○	○	○	○	○	○	1 cup	○	○	○
SWEETS													
Ice cream	○	○	○	○	○	○	○	○	○	1 scoop or 1/2 cup	○	○	○
Doughnuts, cookies, cake, pastry	○	○	○	○	○	○	○	○	○	1 piece or 3 cookies	○	○	○
Pumpkin pie, sweet potato pie	○	○	○	○	○	○	○	○	○	1 medium slice	○	○	○
Other pies	○	○	○	○	○	○	○	○	○	1 medium slice	○	○	○
Chocolate candy	○	○	○	○	○	○	○	○	○	1 small bar or 1 oz	○	○	○
Other candy, jelly, honey, brown sugar	○	○	○	○	○	○	○	○	○	3 pieces or 1 tblsp.	○	○	○



TYPE OF FOOD	HOW OFTEN									HOW MUCH			
	NEVER OR LESS THAN ONCE PER MONTH	1-3 PER MON	1 PER WEEK	2-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2-3 PER DAY	4-5 PER DAY	6+ PER DAY	MEDIUM SERVING	YOUR SERVING SIZE S	M	L
BEVERAGES (Please note that the categories for these columns are different.)													
Whole milk and beverages with whole milk (not incl. on cereal)	○	○	○	○	○	○	○	○	○	8 oz. glass	○	○	○
2% milk and beverages with 2% milk (not including on cereal)	○	○	○	○	○	○	○	○	○	8 oz. glass	○	○	○
Skim milk, 1% milk or buttermilk (not including on cereal)	○	○	○	○	○	○	○	○	○	8 oz. glass	○	○	○
Regular soft drinks (not diet soda)	○	○	○	○	○	○	○	○	○	12 oz can or bottle	○	○	○
Beer	○	○	○	○	○	○	○	○	○	12 oz can or bottle	○	○	○
Wine or wine coolers	○	○	○	○	○	○	○	○	○	1 medium glass	○	○	○
Liquor	○	○	○	○	○	○	○	○	○	1 shot	○	○	○
Coffee, regular or decaf	○	○	○	○	○	○	○	○	○	1 medium cup	○	○	○
Tea (hot or iced)	○	○	○	○	○	○	○	○	○	1 medium cup	○	○	○
Lemon in tea	○	○	○	○	○	○	○	○	○	1 teasp	○	○	○
Non-dairy creamer in coffee or tea	○	○	○	○	○	○	○	○	○	1 tablesp	○	○	○
Cream (real) or Half-and-Half in coffee or tea	○	○	○	○	○	○	○	○	○	1 tablesp	○	○	○
Milk in coffee or tea	○	○	○	○	○	○	○	○	○	1 tablesp	○	○	○
Sugar in coffee or tea	○	○	○	○	○	○	○	○	○	2 teaspoons	○	○	○
Glasses of water	○	○	○	○	○	○	○	○	○	8 oz. glass	○	○	○

18.

SUMMARY QUESTIONS	AVERAGE USE LAST YEAR								
	LESS THAN ONCE PER WEEK	1-2 PER WEEK	3-4 PER WEEK	5-6 PER WEEK	1 PER DAY	1 1/2 PER DAY	2 PER DAY	3 PER DAY	4+ PER DAY
a. How often do you use fat or oil in cooking?	○	○	○	○	○	○	○	○	○
b. About how many servings of vegetables do you eat, not counting salad or potatoes?	○	○	○	○	○	○	○	○	○
c. About how many servings of fruit do you eat, not counting juices?	○	○	○	○	○	○	○	○	○
d. About how many servings of cold cereal do you eat?	○	○	○	○	○	○	○	○	○

THANK YOU VERY MUCH FOR TAKING THE TIME TO FILL OUT THIS QUESTIONNAIRE

Please take a moment to fill in any questions you may have skipped.

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TO BE COMPLETED BY INTERVIEWER:

Interviewer's ID#: ___ ___ ___
Intake was: (Circle one)

- 1 Typical
- 2 Considerably more than usual
- 3 Considerably less than usual

Information was: (Circle one)

- 1R
- 2UTR
- 3UR

Collection method: (Circle one)

- 1 Recall
- 2 Record

Visit #: ___ ___ ___

To be completed by TNDC:

Date coded: ___ ___-___ ___-___ ___
m m d d y y
Date Checked: ___ ___-___ ___-___ ___
m m d d y y

Coder ID#: ___ ___ ___

Checker ID#: ___ ___ ___

Form - N-1

FOOD RECORD

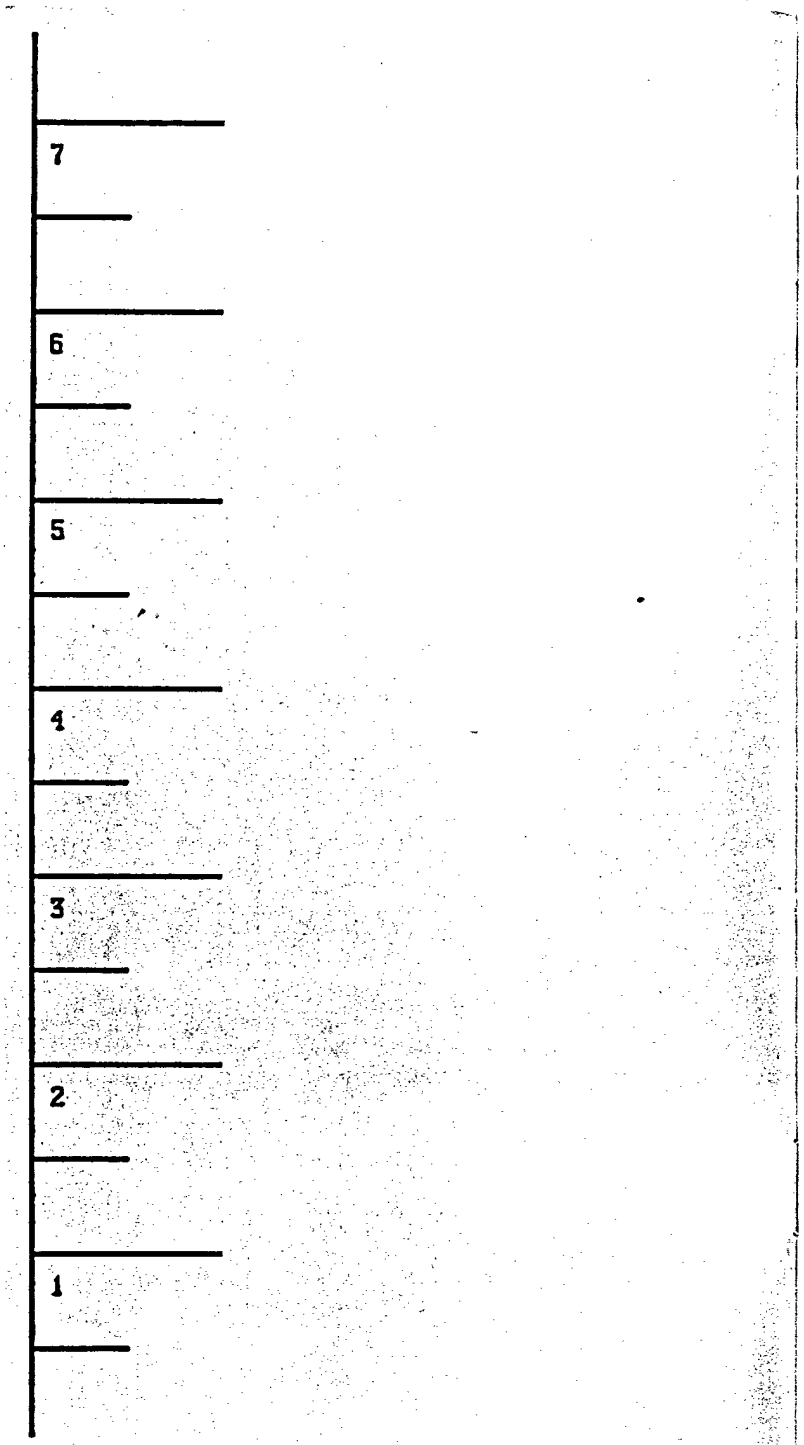
Date of Intake: ___ ___ - ___ ___ - ___ ___
m m d d y y

Participant's ID#: ___ ___ ___

Participant's Sex: M F (Circle)

Birth Date: ___ ___ - ___ ___ - ___ ___
m m d d y y

Interviewer's ID#: ___ ___ ___



APPOINTMENT INFORMATION:

Begin your Record on _____,
day

__ __ - __ __ - __ __ through _____,
m m d d y y day

__ __ - __ __ - __ __.
m m d d y y

Please contact me if any questions arise at:
tel. #:_____

Your next appointment is __ __ - __ __ - __ __.
m m d d y y

Are the three days recorded in this booklet typical of your usual food intake?

Circle: Yes No

If no, explain why?

_____
_____
_____
_____

GUIDELINES FOR KEEPING A FOOD RECORD

1. 3 Day Food Record: Start your food record at midnight (12:01 a.m.) on day one and keep it until midnight (12:00 p.m.) on the last day. Include one weekend day.

2.Record foods and beverages immediately after eating or drinking.

- use pen
- include vitamin and mineral supplements and over-the counter medications

do not change present eating habits during collection of food record

- include all meals, snacks and beverages actually consumed anytime of the day or night.
- if "diet" or other special product, copy nutrition information from label
- include type and amount of added fat, all seasonings, sauces, and condiments
- use brand name wherever possible

3. Start a new page for each day. Use as many pages as needed.

4. List only one food per line. Skip a line between each meal.

5. Time: Record the time to the nearest hour and whether meal was consumed in A.M. or P.M.

6. Place: Indicate where food was prepared:

- Home = 1; Restaurant = 2, to indicate an expensive restaurant, use Ex and for an inexpensive restaurant, use Inex.
- Other = 3, indicate whether fast food, day care, friend's, delicatessen or cafeteria.

7. Meal: Indicate: Breakfast = B, Lunch = L, Dinner = D, Snack = S.

8. Describing Amounts:

- Measure all liquids using a clear measuring cup and record in cups. (Example: milk, 2% 3/4 C.)
- If scales are not available, measure the portion consumed using tablespoons (TB), teaspoons (tsp), cups (C), inches (in), or list the number of small items (Example: 15 raisins).
- When using your measuring cup to measure solids, report the amount in cups, not ounces. (Example: 1 cup cereal).
- If describing a portion in inches, use appropriate measurements, such as:
  - spherical food diameter, e.g. orange, 3" d
  - round food: diameter and height, e.g., cookies, 3" d x 1/4" ht.
  - square or rectangular food: length, width and height, e.g. brownie, 2" l x 3" w x 1/2" ht.
  - wedge food: arc, height and length, e.g. pie, 3" arc x 1" ht x 4" l or diameter of whole and proportion, (e.g.) 1/8th of 8" pie.

9.Describing foods, beverages and supplements:

PROTEIN FOODS:

Meat, Fish, and Poultry:

- cooked or raw weights, trimmed, partially trimmed or untrimmed
- with or without bone/shell
- method of preparation
- type, cut or part, grade or % fat
- light or dark poultry
- with or without skin
- oil or water packed fish

Protein (continued)

Legumes, Nuts and Seeds:

- dry or cooked weights

Eggs and Substitutes:

- size
- method of preparation

Soups:

- cream, milk (%) or water-based
- regular or chunky
- modified or regular

FATS AND OILS:

- brand
- form (stick, tub, liquid)
- type (regular, light, diet, unsalted)

MILK PRODUCTS:

- type or percent fat
- dairy or non-dairy
- liquid or powder

GRAINS AND MIXTURES:

- type of grain or flour
- recipe if homemade or mix
- thick or thin crust pizza

Desserts:

- single or double crust pies
- cake or yeast donut

VEGETABLES AND MIXTURES:

- cooked or raw weight
- method of preparation
- fresh, frozen or canned

FRUIT AND MIXTURES:

- fresh, frozen, canned or dried
- cooked or raw weight
- sweetened or unsweetened

SWEETS:

- description or recipe

BEVERAGES:

Alcohol And Other Beverages:

- proof
- amount without ice
- light or regular beer
- table or dessert wine
- liquor or liqueur
- regular or diet
- with or without caffeine
- brewed or instant
- decaffeinated or herbal tea and coffee

SEASONINGS:

Include all -

- herbs and spices
- condiments and sauces
- meat tenderizer and MSG
- salts - regular or modified, plain or seasoned
- use measuring spoons if possible
- include all additions in cooking or at the table

SUPPLEMENTS AND OVER THE COUNTER MEDICATIONS:

- brand and complete name
- number of tablets or size of dosage taken

10. Recipes: For each recipe used

- Record no more than one ingredient per line.
- If the recipe is consumed again, indicate the new serving size in the same measurements as before.
- No cooking directions are required.
- Record total yield of recipe and amount eaten in the same measurement, or record proportion of total recipe eaten.

11.After completing your food record, go back to the guidelines and check each item listed to make sure you have followed all the instructions.

Circle Day: Su M T W TH Fr Sa **Date: __ __-__ __-__ __**

	Time	Place	Meal	FOOD/BEVERAGE DESCRIPTION		Amount	Coder Use
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							
21							
22							

Medical Questionnaire
(Postmenopausal Women)

Today's Date: ____/___/____
MM/DD/YY

Code #:_____ Date of Birth: ____/___/____ Age:___
MM/DD/YY

Height: _____(feet, inches) Weight: _____(lbs)

Phone: Day (____)_____ Evening (____)_____

In case of Emergency Call: _____ Phone: (____)_____

Marital Status: S M W D

Race: Black ____ White ____ Latino _____ Other _____

Education: Grades Completed (1-12)_____ College (years)_____
Post-college (years) _____

Family History of Disease

Please circle any of the following which any of your blood relatives have had, specify the blood relatives and the age of onset for each condition:

DIABETES

HIGH BLOOD PRESSURE

MIGRAINE HEADACHES

ASTHMA

EPILEPSY

GOUT

PARALYSIS

ARTHRITIS

OSTEOPOROSIS

OSTEOMALACIA

CANCER (please specify type) BREAST COLON OTHER

DEAFNESS

GLAUCOMA

BLEEDING TENDENCY

TUBERCULOSIS

HAY FEVER

NERVOUS SYSTEM DISEASE

ULCERS

HEART DISEASE

KIDNEY DISEASE

Pregnancy History

1. Have you ever been pregnant? ____No _____Yes

If Yes: a. How many times have you been pregnant? _____

b. What was your age when you were first pregnant? _____

c. What was your age when your first child was born? _____

d. How many full-term pregnancies did you have? _____

Number of cesaerean sections _____

e. How many pregnancies were not completed? _____

Number of miscarriages _____

Number of abortions _____

e. What was your age at your last pregnancy? _____

2. Did you breast feed any of your children? _____No ____Yes

If yes, please state how old each of your children is now and the number of weeks/months each child was breastfed:

	Current Age Of Child	Months/ Weeks Breastfed			Current Age Of Child	Months/ Weeks Breastfed	
First child	_____	_____	_____	Fifth child	_____	_____	_____
Second child	_____	_____	_____	Sixth child	_____	_____	_____
Third child	_____	_____	_____	Seventh child	_____	_____	_____
Fourth child	_____	_____	_____	Eighth child	_____	_____	_____

Menstrual History

3. At what age did your menstrual periods begin? _____

4. Have you ever had irregular menstrual cycles? ____ No ____ Yes

If yes: a. How often did you have irregular menstrual cycles?

____ rarely

____ consistently or often

____ just before menopause

____ other:

Explain:_____

5. Have you ever had heavy menstrual flow or severe pain with menstruation? _____ No _____ Yes

6. Have you ever had an abnormal PAP smear? _____ No _____ Yes

If yes: a. How many times? _____

b. Was this within the last five years? _____ No _____ Yes

7. How frequent were your menstrual periods? _____

(from start of one cycle to start of next cycle)

History of Hormone Use Before Menopause
(Note: Menopause is defined as: <u>one year</u> after <u>complete absence</u> of menstrual cycle)

8. Did you ever use birth control pills? _____ No _____Yes
   If yes: a. How old were you when you first used birth control pills?_____
   b. Please indicate in each 10-year age grid below your estimate of how long (in years/months/weeks) you were on birth control pills before menopause:

20 years and below	21-30 years	31-40 years	41-50 years	51-60 years

   c. Please estimate how long (in total) you were on birth control before menopause? _____

9. Did you ever use other methods of birth control? _____ No _____Yes
   If yes: Please explain:_____

10. Did you ever use hormones (other than birth control pills) before menopause?
    _____ No _____Yes. If Yes, please specify_____
    If yes: a. How old were you when you first used hormones?_____
    b. Please indicate in each 10-year age grid below your estimate of how long (in years/months/weeks) you were on hormones before menopause:

31-40 years	41-50 years	51-60 years

c. Please estimate how long (in total) you were on hormones before menopause? _____

11. Did you ever use any fertility medications? _____ No _____ Yes
    If yes: Which one did you use? Please check, and indicate how long you used them:
    ____ DES _____ (months/years)
    ____ Not sure _____ (months/years)
    ____ Other: _____ (months/years)

Menopausal History

12. Have you had a period during the last year?_____ No ____Yes ____Uncertain

13. When was your last menstrual period? ____/_____
    MM/ YY

14. What was your age when you entered menopause (i.e., when you stopped getting your periods completely)? _____

15. Was your menopause? _____ Natural
_____ Surgical/hysterectomy **(Go to 15a)**
_____ Other_____

a. If surgical, did it include removal of ovaries? ____No ____Yes
If Yes: ____ one ovary ____ both ovaries
____ don't know

b. If your menopause was natural, did you have any ovaries removed after menopause?
____ No _____ Yes. If Yes, ____ one ovary ____ both ovaries _____Uncertain

Postmenopausal Hormone Use History

16. Are you currently taking hormones? _____ No _____ Yes
If yes: Please indicate how long you have been taking the hormones: _____

17. Have you taken hormones in the past since menopause (i.e., one year after you stopped getting your period completely)? _____ No _____Yes
    a. If Yes, please indicate in each 10-year age grid below your estimate of how long (in years/months/weeks) you were on hormones after menopause:

31-40 years	41-50 years	51-60 years	61-70 years

b. Please estimate how long (in total) you were taking hormones after menopause:_____

18. When did you stop taking all hormones? _____ months ago/
_____years ago
Date if known: _____ to _____

History of Breast Problems

19. Have you ever had breast cancer?_____No _____ Yes
If yes: What was the date of the diagnosis? _____

20. Have you ever had breast surgery? _____ No _____ Yes
If yes: please explain:_____

21. Have you ever had a biopsy proven adenoma (benign tumor) of the breast?
_____ No ____ Yes

22. Have you ever had any other type of breast problem? ____ No _____ Yes
If yes, please explain: _____

Personal Medical History

23. Do you have a history of:

Medical Conditions	No	Yes
High blood pressure		
Heart Disease		
Diabetes Mellitus		
Pancreatic Disease		
Liver Disease		
Bleeding Disorder		
Hyperlipidemia (high fats in blood)		
Kidney disease		
Small Bowel Disease		
Atrophic Gastritis		
Cancer		
Prior radiation to the chest or breast		
Thyroid Disease		
Urinary tract infection		
Other		

24.What was the date of your last physical exam? _____

25. Please circle Yes or No to the operations and surgeries you have had in the Table below:

Type Of Operation			If Yes, Please Explain And Specify Date Of Operation:
Bowel removal	Yes	No	
Gall Bladder removal	Yes	No	
Operation for Cancer	Yes	No	
Uterus removal	Yes	No	
Ovary removal	Yes	No	
Adrenal removal	Yes	No	
Thyroid removal	Yes	No	
Liposuction/ Fat Tissue removal	Yes	No	
Other:	Yes	No	

26. Please list all prescribed medications you are currently taking, indicate the condition being treated and the date you started taking the medication,

Prescribed Medications	Condition being treated /amounts & frequency used	Date Medication Started

27. Please list all supplements/herbal medications you are currently taking for menopause/other purposes, indicate the condition being treated and the date you started taking these supplements/herbal medications,

Supplements/ Herbal Medications	Condition being treated /amounts & frequency used	Date Medication Started

Weight History

28. Has your weight changed more than 10 lbs in the last 6 months?
_____ No _____ Yes
If Yes, explain: _____

29. Please give your weight (as best you can remember) at age 18? _____ (lbs)
_____ can't remember

30. Please give your weight (as best you can remember) at menopause (i.e., one year after you stopped getting your periods completely)? _____ (lbs) _____ can't remember

Smoking History and Alcohol Intake

31. Are you currently a smoker? _____No _____ Yes
If Yes:
How many cigarettes do you smoke each day? _____

32. Have you smoked a total of 100 cigarettes in your lifetime ? _____No _____ Yes

If Yes:

a. How old were you when you began to smoke cigarettes? _____ years

b. How old were you when you last smoked cigarettes ? _____ years

Please specify date (as best you can remember) when you last smoked cigarettes:_____

c. How many cigarettes did you usually smoke each day/week/month?
Estimated number of cigarettes smoked: _____ each day
_____ each week or
_____ each month

33. Have you ever lived in the same house with a smoker? _____No _____ Yes
If yes:
For how many years did you live with a smoker? _____

34. Do you drink one or more alcoholic beverages per week? No _____ Yes_____
If yes: How many alcoholic drinks do you have per week? _____

The Nurses' Health Study II Activity and Inactivity Questionnaire

32. *During the past year, what was your average time per week spent at each of the following recreational* activities?	Zero min.	1-4 min.	5-19 min.	20-59 min.	One hr.	1-1.5 hr.	2-3 hr.	4-6 hr.	7-10 hr.	11+ hr.
• Walking or hiking outdoors (include walking to work)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
• Jogging (slower than 10 min/mile)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
• Running (10 minute/mile or faster)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
• Bicycling (include stationary machine)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
• Calisthenics/aerobics/aerobic dance/ • rowing machine	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
• Tennis, squash, or racquetball	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
• Lab swimming	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
• Other aerobic recreation (e.g. lawn mowing)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

33. On average, how many *hours per week* do you spend:	Zero	1 hr.	2-5 hr.	6-10 hr.	11-20 hr.	21-40 hr.	41-60 hr.	61-90 hr.	Over 90 hr.
• Standing or walking around at work?	☐	☐	☐	☐	☐	☐	☐	☐	☐
• Standing or walking around at home?	☐	☐	☐	☐	☐	☐	☐	☐	☐
• Sitting at work or while driving?	☐	☐	☐	☐	☐	☐	☐	☐	☐
• Sitting at home?	☐	☐	☐	☐	☐	☐	☐	☐	☐

34. What is your usual walking pace outdoors?

☐ Easy, casual (less than 2 mph) ☐ Normal, average (2-2.9 mph) ☐ Brisk pace (3-3.9 mph)

☐ Very brisk/striding (4 mph or faster) ☐ Unable to walk

35. How many *flights* of stairs (not individual steps) do you climb daily?

☐ 2 flights or less ☐ 3-4 ☐ 5-9 ☐ 10-14 ☐ 15 or more flights

Appendix 3: Body Fat Phenotypes, Sex Hormones and Breast Cancer Risk in Postmenopausal African-American Women

Eligibility Criteria

Weight, Body Fat Phenotype and Level of Obesity Criteria:

1. Must be within 80-150% of ideal body weight based on the Metropolitan Height and Weight Table
2. Must not currently be on a weight loss regimen or trying to lose weight.
3. Weight must be stable (within 10 lbs) for the last 6 months. If more than 250 lbs must not have lost more than 5% of body weight in the last 6 months.
4. LBF phenotype (WHR≤0.75) (N=70; 35 Obese and 35 Non-Obese LBF phenotype women)
   NBF phenotype (0.75<WHR≤0.80) (N=70; 35 Obese and 35 Non-Obese NBF phenotype women)
   UBF phenotype (WHR> 0.80) (N=70; 35 Obese and 35 Non-Obese UBF phenotype women)

   Note: Obese: BMI>27; Non-Obese: BMI≤27 (LBF, NBF, and UBF phenotypes as well as Obese and Non-Obese status similar criteria as used in premenopausal women study)

Race/Ethnicity:

1. Must consider themselves Black, African-American or of African descent

Age Criteria:

1. Must be at least one year postmenopausal up through the age of 70 years (must have gone through at least one year of complete absence of menstrual cycle).

Menopausal History:

1. Must have undergone natural menopause.
2. Must have at least one intact ovary (i.e., qualify if underwent hysterectomy and ovariectomy for removal of one ovary after menopause).

Diet Criteria:

1. Must not be vegetarian.
2. No history of unusual eating habits such as "crash" diets, unusual coping habits (e.g., bingeing or food sprees) or failure to consume a consistent diet are excluded.
3. No megavitamin dosing on a regular basis.
4. Regular use of any over the counter supplements or herbal medications must be documented.

5. Must not consume more than 3 servings of soy/soy products per week (1 serving =1/2 C soybeans; 1C soymilk; 4 oz. Tofu/tempeh;1T miso).

Family/Self History of Breast Cancer/Self History of Other Diseases:

1. No family history of breast cancer (no mother, sister, daughter, father, brother, son with breast cancer – i.e., no first degree relatives with breast cancer).
2. No personal history of cancer, heart disease, diabetes mellitus, renal, thyroid disease, liver or bowel disease, or any other major illness (sickle cell trait okay).
3. No biopsy proven adenomas of the breast and no history of breast surgery. If diagnosed with benign breast disease need to sign "Medical Release Form" for release of diagnosis report from physician. Only women with benign breast disease not associated with increased risk of breast cancer would be eligible.
4. Must not be HIV positive.

Alcohol Intake:

1. Do not consume alcohol on a regular basis (i.e., not more than a drink a week/1 oz of alcohol a week).

Smoking:

1. Must be a non-smoker or must have stopped smoking for at least 6 months.

Prescribed Medications:

1. Do not use prescribed medications. If on prescribed medication recently, refer to Dr. Gorbach (tel: 636-3811) for information on how long must be off medication before eligible, if Dr. Gorbach is not available please call Dr. Richard Seigel (tel: 636-5689) or Dr. Bess Dawson-Hughes (tel: 556-3066), e.g.:
   a. corticosteroids (e.g., oral glucocorticoids – must have stopped taking within the last 3 months),
   b. antibiotics (must have stopped taking within the last 2 months),
   c. other drugs?? Consult study consultants listed above.

Exogenous Hormones

1. Not currently using any exogenous hormones for at least 6 months.
2. No hormone replacement therapy (HRT) during the past 6 months.
3. Women with cumulative hormone use of less than 10 years after menopause (i.e., one year after complete absence of menstrual period.

Physical Activity Level:

1. Must be mobile but not training for any athletic competition (as in premenopausal women study). Must have stopped athletic training for 6 months prior to participation in the study.

Appendix 4: Approved study flyers, and brochure

NEMCH/TUHS
HIRC

☒ Approved
☐ Approved as Noted

Signature 4354 Date 2/7/00

Nutrition Unit, Department of Family Medicine and Community Health, Tufts Medical School

136 Harrison Avenue • Arnold 205 • Boston, MA 02111 • Tel: 617-636-6792 • Fax: 617-636-3810

Date:

To: NEMC News
Box 810

From: Laura Snydman
Project Coordinator
617-636-6972

Re: Ad for the NEMC News

Please place the following ad in the next four issues of the NEMC News. A check for $16.00 has been enclosed. If there are questions please give me a call. Thank you.

ATTENTION!! ALL BLACK WOMEN AFTER MENOPAUSE. The Nutrition Unit at Tufts Medical School is seeking Black women after Menopause to participate in a "Breast Cancer Risk" research study. **PLEASE CALL 617-636-6972. Get your percent body fat measured free and receive $100.** Minimum 3 visits required. Must be 1 year postmenopausal up to age 70, non-smoking, non-vegetarian, and not taking any hormones.

NEMCH/TUHS
HIRC
☒ Approved
☐ Approved as Noted
Signature 4354 Date 2/17/00

Black Women
After Menopause

Participate in a Breast Cancer Risk Research Study

RECEIVE $100
Minimum 3 Visits Required

IF YOU ARE:

- 1 Year Postmenopausal
  Up To Age 70
- Non-Smoking
- Non-Vegetarian
- Not Taking Any Hormones

PLEASE CALL: (617) 636-6972

WE NEED YOUR HELP!

This research study is conducted by the Nutrition Unit at Tufts Medical School - Boston, MA

NEMCH/TUHS
HIRC
☒ Approved
☐ Approved as Noted
Julia A. Tetrault 2/17/00
Signature 4354 Date

ATTENTION!!!

Black Women

After Menopause

Participate in a Breast Cancer Risk Research Study

RECEIVE $100

Minimum 3 Visits Required

IF YOU ARE:

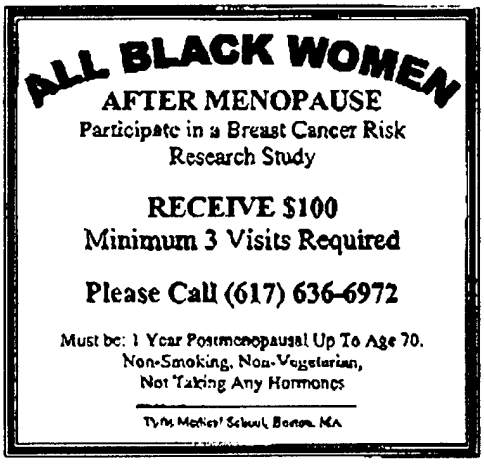
- 1 Year Postmenopausal
  Up To Age 70
- Non-Smoking
- Non-Vegetarian
- Not Taking Any Hormones

PLEASE CALL: (617) 636-6972

WE NEED YOUR HELP!

This research study is conducted by the Nutrition Unit at Tufts Medical School - Boston, MA

NEMCH/TUHS
HIRC
☒ Approved
☐ Approved as Noted
Signature 4354 Date 2/17/00



NEMCH/TUHS
HIRC

☒ Approved
☐ Approved as Noted

Signature 4354 Date 2/17/00

ATTENTION!

BLACK WOMEN
AFTER MENOPAUSE

Participate in a Breast Cancer Risk Research Study

RECEIVE $100
Minimum 3 Visits Required

If you are:

- 1 Year Postmenopausal Up To Age 70
- Non-Smoking
- Non-Vegetarian
- Not Taking Any Hormones

PLEASE CALL: (617) 636-6972

WE NEED YOUR HELP!

This research study is conducted by the Nutrition Unit at Tufts Medical School - Boston, MA

NEMCH/TUHS
HIRC
☒ Approved
☐ Approved as Noted
Signature 4354 Date 2/17/00

NEMCH/TUHS
HIRC

☒ Approved
☐ Approved as Noted

Signature 4354 Date 2/17/00

ATTENTION BLACK WOMEN
AFTER MENOPAUSE
Participate in a Breast Cancer Risk Research Study
At Tufts Medical School
RECEIVE $100
Minimum 3 Visits Required
Call (617) 636-6972
Must be: *1 Year Postmenopausal Up To Age 70,*
NON-Smoking, NON-Vegetarian,
NOT Taking Any Hormones

NEMCH/TUHS
HIRC
☒ Approved
☐ Approved as Noted
Signature 4354 Date 2/17/00

Attention!
All Black Women
After Menopause

Participate in a Breast Cancer Risk Research Study
Receive $100

Minimum 3 Visits Required

Must be:

- 1 Year Postmenopausal Up To Age 70
- Non-Smoking
- Non-Vegetarian
- Not Taking Any Hormones

Please call: (617) 636-6972
We Need Your Help!

This research study is conducted by Tufts Medical School - Boston, MA

NEMCH/TUHS
HIRC
☒ Approved
☐ Approved as Noted
Signature 4354 Date 2/17/00

ATTENTION!!!
Black Women
After Menopause

Participate in a Breast Cancer Risk Research Study

RECEIVE $100
Minimum 3 Visits Required

IF YOU ARE:

- 1 Year Postmenopausal Up To Age 70
- Non-Smoking
- Non-Vegetarian
- Not Taking Any Hormones

PLEASE CALL: (617) 636-6972

WE NEED YOUR HELP!

This research study is conducted by the Nutrition Unit at Tufts Medical School - Boston, MA

THE FACTS ABOUT BREAST CANCER IN BLACK WOMEN

Breast cancer is the second leading cause of cancer death among Black women in the U.S., exceeded only by lung cancer. In 1999, the estimated number of Black women in the U.S. newly diagnosed with breast cancer is 18,100 and approximately 5,600 Black women are expected to die from breast cancer. The breast cancer death rates among Black women is still approximately 20% higher than White women. Only 71% of Black women survive for 5 years after having been diagnosed with breast cancer compared to 87% of White women.*

WHAT IS THIS STUDY ABOUT?

The Nutrition Unit, Department of Family Medicine and Community Health, Tufts University School of Medicine, is conducting a Body Fat Distribution and Risk of Breast Cancer Study in Black women after menopause. This research study is funded by the Department of Defense Breast Cancer Research Program. The study would help identify if fat deposited on the waist and the abdomen verses fat deposited in the buttocks and thighs among postmenopausal Black women influences sex-hormone levels, and consequently their risk for developing breast cancer.

WHAT IS THE IMPORTANCE OF THIS STUDY?

There are very few risk factors of breast cancer that can be changed. The distribution of body fat can be changed by changing life style factors such as smoking, diet, intake of alcohol and physical activity level. The identification of body fat distribution as a marker of increased risk of breast cancer is thus very important as it has the potential to decrease a women's risk of getting the disease, and to alert women at high risk to take appropriate actions which can help save their lives.

* Data obtained from the American Cancer Society "Cancer Facts & Figures for African Americans 1998-1999".

WHAT ARE MY RESPONSIBILITIES IF I PARTICIPATE?

Over the phone you will be asked a few questions in order for us to fill out a telephone screening questionnaire. Then a 20 to 30 minute screening appointment will be scheduled. At the screening appointment we will measure your waist and hip circumferences, as well as your height and weight. If you are eligible we will provide you with a small packet of materials for further screening. The screening packet includes questionnaires, a four day food record booklet and a diet scale.

After we receive your screening packet and confirm your eligibility, it is required that you come to the New England Medical Center on two consecutive mornings to provide blood samples. There will also be a one hour appointment to take body measurements during one of those days as well as a 20 minute appointment for a total body scan.

WHY WOULD I WANT TO ENROLL IN THIS STUDY?

- Satisfaction that you have contributed to an important cause in an area of research that has the potential to benefit Black women, in particular, and breast cancer research in general,
- FREE laboratory evaluation of your blood cholesterol, other lipid and lipoprotein levels that will give you an indication of your risk of getting heart disease,
- FREE evaluation of your food intake, including the recommended food and nutrient intake guidelines,
- FREE analyses of your body composition using several up-to-date techniques, including information on your percent body fat and lean body mass, and
- Receive $100.00 in appreciation for your invaluable contribution to the study.

WE WILL ALSO MAIL YOU A COPY OF THE FINAL STUDY REPORT OF OUR FINDINGS, IF YOU WISH, AND IF YOU LEAVE US A PERMANENT ADDRESS!

HOW CAN I HELP?

1. Call us to volunteer to participate in the study, we need a lot of women,
2. Tell your family members, friends, and co-workers about the study,
3. Help us distribute and put up our flyers at places where women of African descent are more likely to see it, and if you need more flyers, please call us for more. (Suggested places for putting up flyers: your workplace, laundromats, libraries, gyms, churches, grocery stores, et cetera.),
4. Call us if you have any idea at all about agencies, people, and any other contacts and functions where we can reach Black women after menopause up to the age of 70 years,
5. Call us to arrange for a presentation to groups of postmenopausal Black women and to provide more information about the study.

THANK YOU FOR YOUR TIME AND FOR ANY HELP YOU CAN PROVIDE US

"Body Fat Distribution and Risk of
Breast Cancer Study in Black Women After Menopause"

Junaidah B. Barnett, Ph.D., Principal Investigator
Laura Snydman, Research Coordinator
Lorraine Hector, Enrollment Coordinator

Dept. of Family Medicine and Community Health - Nutrition Unit
Tufts University School of Medicine
136 Harrison Avenue-Arnold 205
Boston, MA 02111
Tel: (617) 636-6972

APPENDIX 5: Study recruitment status

New England Medical Center
A Lifespan Partner

TUFTS UNIVERSITY
SCHOOL OF MEDICINE

BARNETT, JUNAIDAH PHD
BOX ST-203
COMMHLTH
TUSM

N.A. Mark Estes, III, M.D.
Professor of Medicine,
Tufts University School of Medicine
Chairman, HIRC

Judy A. Tesnow
Administrator

Re: BODY FAT PHENOTYPES, HORMONES, AND BREAST CANCER IN POSTMENOPAUSAL AFRICAN-AMERICAN WOMEM (DOD)

Login No.: 4354

PROTOCOL CHANGES ADMINISTRATIVELY APPROVED DATE: **10/02/00**

Amendment #: _____ dated:_____ Contact Letter: ___X___

Addendum #: _____ dated:_____ Other: Flyer_____

Revision: ___X_____ dated: __08/22/00

CONSENT FORM(S): (incorporating protocol changes)

Administratively Approved as Revised: _____ Number of Consent Forms:___

Enclosed for use is a copy of each approved and validated consent form which has been dated with the date of administrative approval and is valid until the date of re-certification. Please discard earlier versions.

Must be Revised (see attached copy with changes): _____

No Consent Form Changes: _____

Not Applicable: _____

COMMENTS: Approval is granted to change the eligibility criteria from the original 4 years postmenopausal to one year postmenopausal.

Please note that the protocol must undergo full Committee approval at the re-certification date.

Judith Strauss RN M.Ed 10-2-00
Signature of Chairman, Vice Chairman, HIRC Member DATE

Cc: Abby Sheritz, MD

THIS LETTER MUST BE RETAINED FOR YOUR RESEARCH FILES.

Black Women after Menopause
You Can Make A Difference !

Black Women have the highest Breast Cancer Death Rate in the U.S.

Participate in a Breast Cancer Risk Research Study

Receive $100 - minimum 3 visits

Must be:

- 1 Year without Menstrual Periods
- Not over 70 Years Old
- Non-Smoking
- Non-Vegetarian
- Not Taking Any Hormones

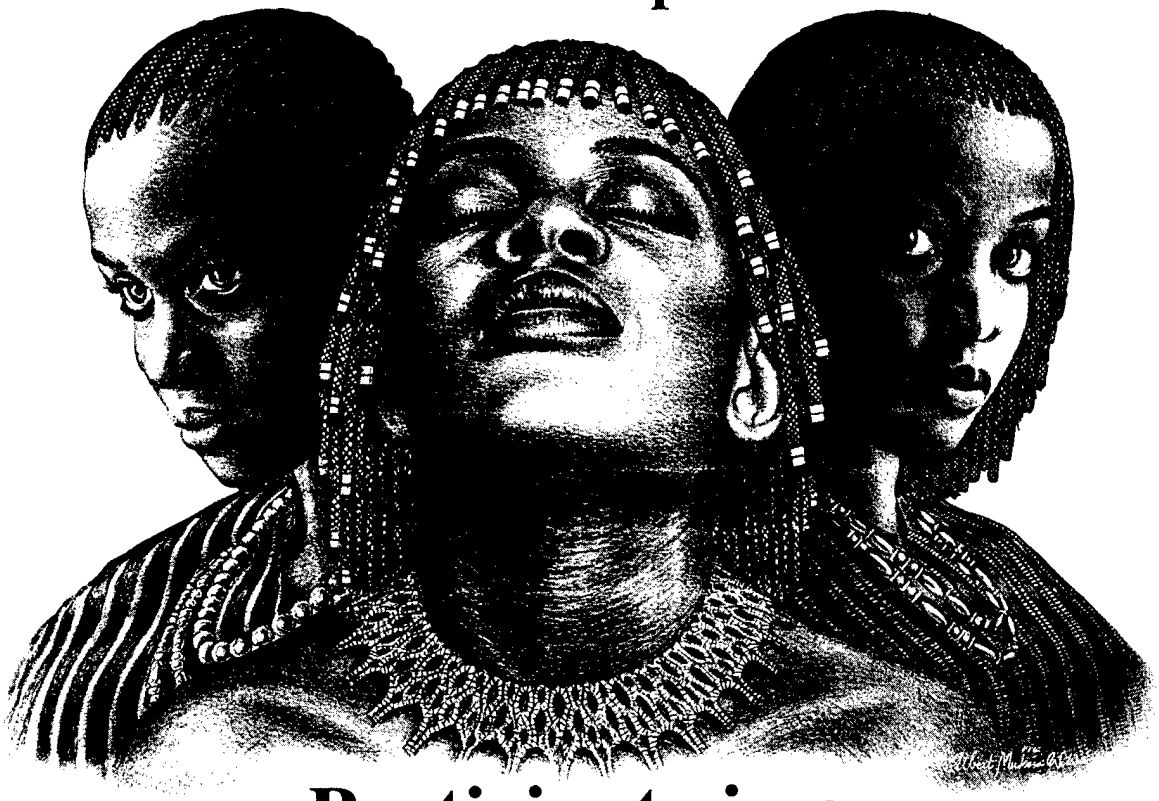
NEMCH/TUHS HIRC
☐ Approved
☐ Approved as Noted
Signature 10-2-02 Date
4334

Help this Important Cause in the Black Community!

Please Call: (617) 636-6972 ANYTIME

This research study is conducted by Tufts Medical School - Boston, MA

Attention!
All Black Women
After Menopause



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We Need Your Help!

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Please Inform Other Women About this Study

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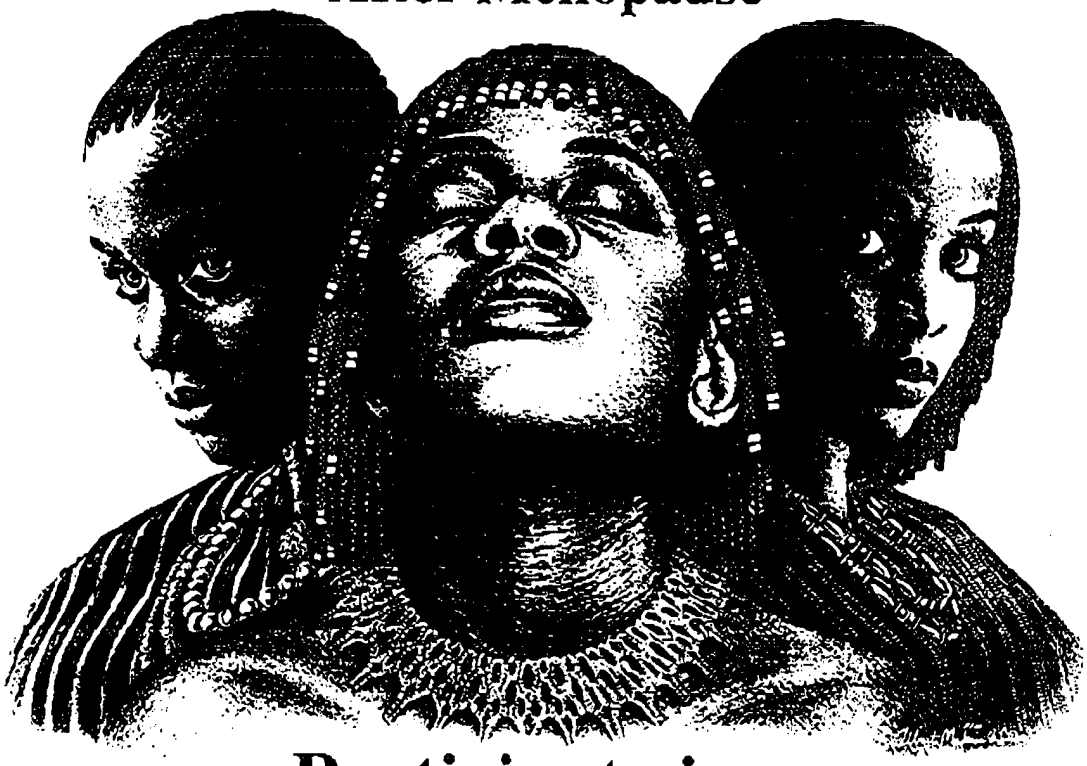

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Date

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To whom it may concern:

Breast cancer death rates are highest in Black women
compared to women in other ethnic groups in the U.S.

YOU CAN HELP MAKE A DIFFERENCE!

1. We are looking for Black women whose menstrual cycles have stopped completely over a period of one year up to 70 years of age to participate in a research study to determine breast cancer risk factors in the postmenopausal Black women population. Women who may qualify will be further screened for eligibility.

2. Even if you may not be eligible for the study, we ask that you please read on because you can still help us spread word about the study to those whom you think may qualify. Please also ask that they pass the word on to other women they know who may qualify. Our experience indicate that word of mouth is one of the best ways to inform women about the study.

3. Please refer to our informational flyer enclosed for information on

"HOW CAN I HELP?"

Research dollars to do studies in the Black population, especially in the postmenopausal Black women population, have been very limited in the past because of lack of confidence that data can actually be collected successfully in this population. We are determined to prove that we can, with help from the Black community, recruit eligible postmenopausal Black women for the study. The information that we will collect for this research study can be of great public health significance to help better identify women at high risk for developing breast cancer. Our findings may also help to more precisely target women for preventative and therapeutic purposes.

Let's work together!
Help us successfully recruit the women we need for this study.

Thank you in advance for the help you may be able to provide us.
With deep appreciation, warm wishes and regards,

Junaidah Barnett, Ph.D.
Principal Investigator
"Body Fat Distribution, and Risk of Breast Cancer
Research Study in Black Women After Menopause"

APPROVED: 10/02/00

VALID THROUGH: 03/31/01

HOW CAN I HELP?

1. Call us to volunteer to participate in the study, we need a lot of women,

2. Tell your family members, friends, and co-workers about the study,

3. Help us distribute and put up our flyers at places where women of African descent are more likely to see it, and if you need more flyers, please call us for more. (Suggested places for putting up flyers: your workplace, laundromats, libraries, gyms, churches, grocery stores, et cetera.),

4. Call us if you have any idea at all about agencies, people, and any other contacts and functions where we can reach Black women after menopause up to the age of 70 years,

5. Call us to arrange for a presentation to groups of postmenopausal Black women and to provide more information about the study.

THANK YOU FOR YOUR TIME AND FOR ANY HELP YOU CAN PROVIDE US

"Body Fat Distribution and Risk of Breast Cancer Research Study in Black Women After Menopause"

Department of
Family Medicine and
Community Health - Nutrition Unit
Tufts University School of Medicine
136 Harrison Avenue - Arnold 205
Boston, MA 02111

Tel: (617) 636-6972

Attention!

All Black Women After Menopause

Participate in a Breast Cancer Risk Research Study

Receive $100
Minimum 3 Visits Required

Must be:
- 1 Year Postmenopausal Up To Age 70
- Non-Smoking
- Non-Vegetarian
- Not Taking Any Hormones

Please call: (617) 636-6972
We Need Your Help!

This research study is conducted by
Tufts Medical School - Boston, MA

THE FACTS ABOUT BREAST CANCER IN BLACK WOMEN

Breast cancer is the second leading cause of cancer death among Black women in the U.S., exceeded only by lung cancer. In 1999, the estimated number of Black women in the U.S. newly diagnosed with breast cancer is 18,100 and approximately 5,600 Black women are expected to die from breast cancer. The breast cancer death rates among Black women is still approximately 20% higher than White women. Only 71% of Black women survive for 5 years after having been diagnosed with breast cancer compared to 87% of White women.*

WHAT IS THIS STUDY ABOUT?

The Nutrition Unit, Department of Family Medicine and Community Health, Tufts University School of Medicine, is conducting a "Body Fat Distribution and Risk of Breast Cancer Study in Black Women after Menopause." This research study is funded by the Department of Defense Breast Cancer Research Program. The study would help identify if fat deposited on the waist and the abdomen verses fat deposited in the buttocks and thighs among postmenopausal Black women influences sex-hormone levels, and consequently their risk for developing breast cancer.

* Data obtained from the American Cancer Society "Cancer Facts & Figures for African Americans 1998-1999".

WHAT IS THE IMPORTANCE OF THIS STUDY?

There are very few risk factors of breast cancer that can be changed. The distribution of body fat can be changed by changing life style factors such as smoking, diet, intake of alcohol and physical activity level. The identification of body fat distribution as a marker of increased risk of breast cancer is thus very important as it has the potential to decrease a women's risk of getting the disease, and to alert women at high risk to take appropriate actions which can help save their lives.

WHAT ARE MY RESPONSIBILITIES IF I PARTICIPATE?

Over the phone you will be asked a few questions in order for us to fill out a telephone screening questionnaire. Then a 20 to 30 minute screening appointment will be scheduled. At the screening appointment we will measure your waist and hip circumferences, as well as your height and weight. If you are eligible we will provide you with a small packet of materials for further screening. The screening packet includes questionnaires, a four day food record booklet and a diet scale.

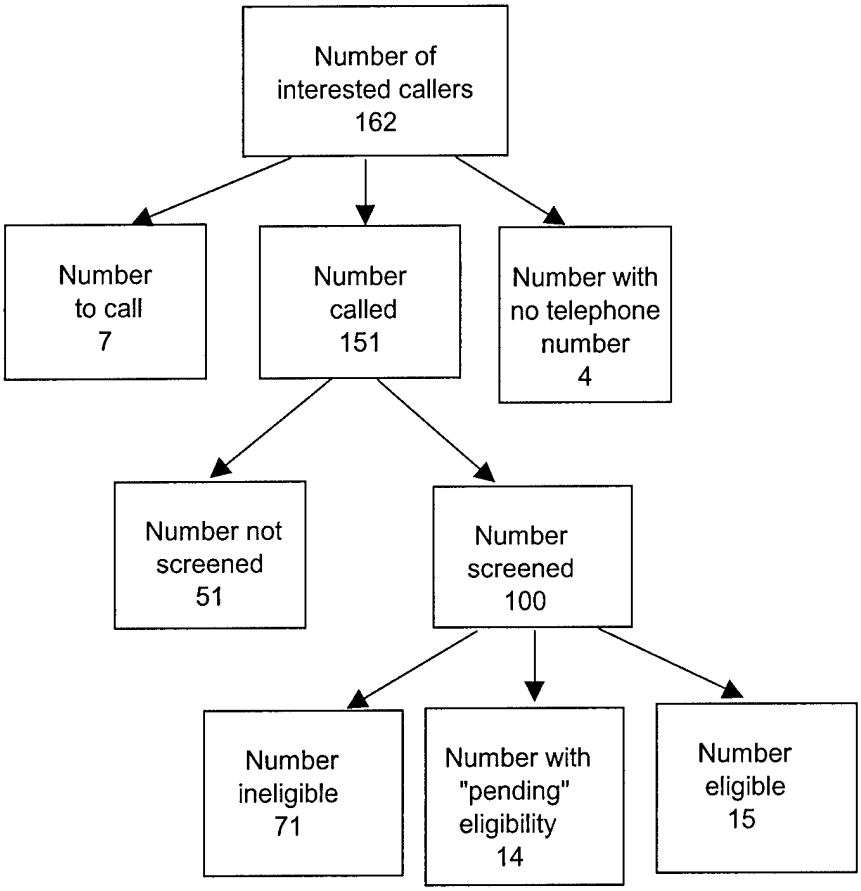
After we receive your screening packet and confirm your eligibility, it is required that you come to the New England Medical Center on two consecutive mornings to provide blood samples. There will also be a one hour appointment to take body measurements during one of those days as well as a 20 minute appointment for a total body scan.

WHY WOULD I WANT TO ENROLL IN THIS STUDY?

- Satisfaction that you have contributed to an important cause in an area of research that has the potential to benefit Black women, in particular, and breast cancer research in general,
- FREE laboratory evaluation of your blood cholesterol, other lipid and lipoprotein levels that will give you an indication of your risk of getting heart disease,
- FREE evaluation of your food intake, including the recommended food and nutrient intake guidelines,
- FREE analyses of your body composition using several up-to-date techniques, including information on your percent body fat and lean body mass, and
- Receive $100.00 in appreciation for your invaluable contribution to the study.

WE WILL ALSO MAIL YOU A COPY OF THE FINAL STUDY REPORT OF OUR FINDINGS, IF YOU WISH, AND IF YOU LEAVE US A PERMANENT ADDRESS!

Appendix 6. Study Recruitment Status



APPENDIX 7: Letter of request for approval

TUFTS UNIVERSITY

School of Medicine

Community Health/Nutrition Infection Unit

To: Ms. Judy Tesnow, HIRC
From: Junaidah Barnett, Ph.D. JB
Re: "Body Fat Phenotypes, Hormones and Breast Cancer in Postmenopausal African-American Women" -- Protocol login #: 4354
Date: August 22, 00

We are writing to request administrative approval from you for changing our eligibility criteria for the above mentioned study from the original 4 years postmenopausal to one year postmenopausal. We have been advised to change this criteria by our study consultants as this is the accepted criteria for the definition of menopause. According to the WHO Scientific Group addressing Research on Menopause[1], the standard definition of menopause is occurrence of a final menstrual period. There is general consensus that amenorrhea for at least 12 months is an acceptable definition in practice. Postmenopause refers to the time after the final menstrual period. Thus for this study, one year postmenopausal will be 12 months after this final menstrual period. This criteria is also suggested to help increase the number of interested women who would qualify for the study given the challenge in recruiting postmenopausal Black women for a research study.

In addition, for the same reason of attempting to increase the number of women eligible for the study, we have also recently decided to change the eligibility criteria from women who consume 30% or more calories from fat in their diet to accepting all eligible women regardless of their levels of fat intake. This criteria is changed with the agreement of our biostatistician who assured us that the percent calories from fat in the diet can be adjusted for in the final study analyses in our multivariate regression analysis model.

We look forward to hearing from you soon with approval for the above-requested changes in our eligibility criteria. Thank you.

[1]World Health Organization Scientific Group (WHO) 1996 Research on the Menopause in the 1990s. WHO Technical Service Report Series No. 866. Geneva: World Health Organization.

136 Harrison Avenue
Boston, Massachusetts 02111
Ph: (617) 636-3811
Fax: (617) 636-3810

New England Medical Center
A Lifespan Partner

TUFTS UNIVERSITY
SCHOOL OF MEDICINE

Junaidah Barnett, PhD
Box ST-203
COMMHLTH
TUSH

N.A. Mark Estes, III, M.D.
Professor of Medicine,
Tufts University School of Medicine
Chairman, HIRC

Judy A. Tesnow
Administrator

RE: BODY FAT PHENOTYPES, HORMONES, AND BREAST CANCER IN POSTMENOPAUSAL AFRICAN-AMERICAN WOMEN (DOD)
Login 4354

Dear Dr. Barnett,

This letter confirms that all of the criteria specified in your August 22, 2000 revision request have been administratively approved in the letter dated 10/02/00. The specific approved amendments include:

1) Change in eligibility criteria from the original 4 years postmenopausal to one year postmenopausal
2) The inclusion of all eligible women regardless of their levels of fat intake

Sincerely,

Judith A Frazier RN

Judith A. Frazier, RN
Vice-Chair
NEMC IRB

Human Investigation Review Committee

750 Washington Street, NEMC #817, Boston, MA 02111
Tel 617 636-7512 Fax 617 636-8394